

The War Against Counterfeit Medicine My Story



Dora Nkem Akunyili

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THE WAR AGAINST COUNTERFEIT
MEDICINE
MY STORY

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COUNTERFEIT MEDICINE
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DORA NKEM AKUNYILI



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DEDICATION

To my beloved sister, Vivian Edemobi whose premature death in 1988 from the use of fake insulin brought the acutely painful message of counterfeit medicine squarely home to me.

To my parents, Chief Paul Young Edemobi and Mrs Grace Udumehie Edemobi, who believed that I would grow up to be great, but never lived to see this day.

To my fellow Nigerians who have either died, been maimed, or suffered worsening disease conditions because of the use of counterfeit medicine. Your losses have been my impetus.

Note: The currency conversions used were correct at time of writing (2008)

FOREWORD

There is a general agreement that piracy; counterfeiting and passing off are unfair. However, there is often surreptitious – or even open – sympathy for, say, those who purchase counterfeit designer fashions or the latest technical gadgets. The *pirate* is sometimes represented as a dared evil hero who, like the historical pirate on the high seas, provides a kind of rough justice. In her book, as in her life, however, Prof. Dora Nkem Akunyili takes on a field in which the damage done by counterfeiting is unequivocal; in which passing off can kill or disable to satisfy the greed of the perpetrators and their sponsors.

Prof. Akunyili's commitment to the fight against counterfeit drugs is deeply rooted in her personal experience. Her younger sister, who was diabetic, died after being treated with fake insulin. Since her appointment as Director General of Nigeria's National Agency for Food and Drug Administration and Control (NAFDAC) in 2001, Prof. Akunyili has struggled against inertia and entrenched vested interests. And she has braved death threats – including an assassination attempt – in order to transform her experiences into action.

Prof. Akunyili stresses the sheer scope of the products involved in counterfeiting, and the variety of their outlets in Nigeria. Apart from counterfeit copies of all the most readily available medicines and prescription drugs found, for example, in pharmacies, clinics and hospitals, there are also counterfeit traditional remedies sold locally; fake cosmetics bought in small stores and smart specialist shops; counterfeit bottled water and drinks sold by supermarkets, street hawkers and cafés; and counterfeit copies of health products such as baby milk and vitamins. These present an all-pervasive danger to unsuspecting consumers.

Neither do people realise quite how many people in, for example, airlines, customs services, bus and rail companies, are involved in the dissemination of such products. No one is spared from risk, from the wealthiest clients of the Hilton Hotel in Abuja, to the poorest families living in a single room in the villages. Prof. Akunyili vividly evokes the hold these products have on national life in Nigeria, and how this is interwoven with the international ramifications of import policy and practice in a country, which, she estimates, needs some 60 per cent of foreign input in the drugs industry.

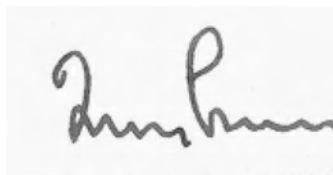
When Prof. Akunyili took up her post as the head of NAFDAC, no hospital, clinic or pharmacy in the country could be certain that the drugs they dispensed were genuine. She recalls the time when NAFDAC registration was given without factory inspection, and when the practice with regard to the grant of import licences tended to undercut deserving local producers, reputable multinational companies and the sale of Nigerian products abroad.

She also underscores the fact that effective enforcement requires considerable resources. These include trained personnel in various fields, some of them extremely specialised; premises to establish institutional presence and to cover inspection and the preservation and safeguard of products; laboratory facilities and equipment; and mobile teams to investigate alarms on an emergency basis in cooperation with law and order authorities. She charts the expansion and spread of NAFDAC offices to cover all 36 states and the Federal Capital Territory. And she illustrates the need for stamina and determination to overcome setbacks – among which was the criminal destruction of NAFDAC property – by improvisation and rebuilding.

Scientific and technological progress bring their own forms of abuses and exploitation, along with their benefits, and methods of prevention and enforcement have to be adjusted to keep pace. Counterfeiters have been quick to exploit, for example, the speed, convenience and anonymity of the Internet as a medium for expanding the sale of drugs.

The War Against Counterfeit Medicine: My Story is a unique study of a global phenomenon – in which lawbreaking and profiteering prevail at the cost of human health and life – and of the ways in which this can be fought by appropriate legislation, regulation and enforcement. The challenges in countering are enormous, not least since such illicit production of food and drugs is an immensely lucrative business. Prof. Akunyili cites statistics from the World Health Organization, noting that in 2003, the worldwide sale of counterfeit drugs accounted for US\$32 billion, or 10 per cent of all drug sales.

Dora Akunyili's achievements as Director General of NAFDAC are an inspiration to everyone, in every country, who is involved in countering the proliferation of fake food and drugs. Her experiences are a message of hope. They are testimony to the commitment and courage of individuals who serve the institutions, which work to ensure that commercial profitability goes hand in hand with the safety and wellbeing of consumers.

A handwritten signature in dark ink, appearing to read 'Francis Gurry', on a light background.

Francis Gurry
Director General
World Intellectual Property Organisation (WIPO)
2009

PREFACE

I decided to write this book entitled: *The War Against Counterfeit Medicine: My Story*, to chronicle my experiences as the Director General (DG) of Nigeria's National Agency for Food and Drug Administration and Control (NAFDAC), between April 2001 and December 2008.

I feel a compelling need to write this book for two reasons. Firstly, to document what my team and I did in over seven and a half years in the fight to protect the public from the fatal consequences of fake medicines and unwholesome food products. It is my hope that it will help compel individuals, organisations and governments to recognise the heightened level of the dangers posed by medication counterfeiters, and thus ensure that strategies that have led to our globally recognised achievements over this period are not jettisoned, but improved upon. Secondly, I believe that the publication will help countries improve on their food and drug regulatory environments and strategies where they already exist, or create new ones where none exists. Considering the fact that drug counterfeiting is an emerging phenomenon, it is understandable that there is currently no clear-cut strategy in any literature on how to tackle the menace. Thus, it is my hope that this publication will contribute to the efforts of regulators all over the world.

The book is divided into five parts of eighteen chapters and gives an overview of many of the events that took place during the period under discussion.

In the prologue, I give some background on my upbringing, growing up and life in a Nigerian village before and during the Nigerian Civil War between 1967 and 1970. Looking back, I have no regrets about the hardship I went through because it prepared me for the life ahead.

As a child, I never thought of studying pharmacy. Medicine was my career of choice and my family's desire for me at the time. However, that did not happen as my love for mathematics and chemistry spurred me to study pharmacy, the course that unexpectedly prepared me for the journey towards becoming the Director General (DG) of NAFDAC.

In the prologue, I tell the story of my journey from academia to public service, starting from 1994, and all the events that led to my being appointed the Director General of NAFDAC. I was encouraged and motivated in the long years of service for many reasons:

First, former President Olusegun Obasanjo appointed me to the position despite stiff opposition from the political class. He believed in my ability to do the job following my performance in my former job at the Petroleum (Special) Trust Fund (PTF). I am also mindful that many families have lost loved ones because of the effects of fake drugs, an experience my family shared with the loss of my favourite sister, Vivian. In addition, I felt the appointment was an opportunity for me to give back to the country that has given so much to me. My entire education, from high school through to university in Nigeria, to doctorate and post-doctoral studies in London, was possible due to government scholarships. Finally, against the barrage of criticisms following my appointment, I was determined to succeed, to prove my critics wrong and to remain uncompromising in my job.

Chapter 1 outlines the historical background of food and drug regulation in Nigeria. It also chronicles the evolution of drug production and sale from the rudimentary era of pre-1957, through the foundation-laying era of the 1960s to the potentially bright post-2001 era.

Chapter 2 outlines the development of food and drug regulation in Nigeria. Taking a cue from the USFDA, which was established in June 1906, NAFDAC was established by Decree No. 15 in 1993.

In Chapter 3, the mandate, structure, functions, laws and regulations by which NAFDAC performs its duties are explained. Decree No. 15 of 1993, mandates NAFDAC to regulate and control the manufacture, importation, exportation, advertisement, distribution, sale and use of food, drugs, medical devices, cosmetics, detergents, chemicals and all packaged drinks, including table water. NAFDAC therefore, has a statutory responsibility to ensure the quality, safety, efficacy and wholesomeness of these items, collectively referred to as regulated products.

Chapter 4 explains the various definitions of fake, counterfeit, adulterated, substandard drugs, unwholesome food and other substandard regulated products. These various definitions show that despite the global nature of fake and counterfeit drugs, the international community has not given the problem the attention it deserves, as evidenced by the non-existence of a harmonised definition. The absence of a universally accepted definition not only makes information exchange among countries very difficult, but also limits their ability to understand the true extent of the problem of counterfeit medicines.

Chapter 5 gives a global overview of drug counterfeiting. Even though drug counterfeiting is a global problem, developing countries are more affected and the poor bear the brunt because they feed poorly and live under unhealthy conditions. They are therefore more predisposed to being sick. Developed countries however, have started to experience an increasing incidence of counterfeit drugs, mostly fuelled by purchase of drugs via the Internet. Recent findings show that the range is from <1 percent of sales in developed countries (but growing) to >10 percent in developing countries, depending on the geographical area. In this chapter, I also present a regional spread of the problem as experienced in Asia, Europe, North America, South America and Africa. I also highlight some major tragedies caused by the use of counterfeit or poorly formulated medications across the world.

In chapter 6, I describe the state of NAFDAC when I assumed office in April 2001. Every part of the organisation was dysfunctional, from employees and the laws to the facilities. I was faced

with the arduous task of reactivating a failed food and drug regulatory environment of over three decades, which had reached crisis point. During that period, criminals had dumped various forms of counterfeit medicines in Nigeria unchallenged. Various forms of unwholesome food, substandard cosmetics, chemicals and related products were also dumped in Nigeria with impunity.

Chapter 7 of the book describes how we waged an all-out war against fake drugs and other substandard regulated products in Nigeria. On assumption of duty, the enormity of the decay in the system was a rude shock, but I refused to be discouraged. Rather, I converted the pressure of a failed system into a positive drive for success. Although I had no clear-cut idea or strategy on how to fight the war, I had an unshakable determination to succeed. In addition, I was pressured into action by the vibrant Nigerian press that was as impatient as the public to see a change in the system. The nationwide public enlightenment campaigns, one of our strategies against medication counterfeiting, began in Lagos on June 21, 2001, and were later extended to all the states of the Federation.

Chapter 8 describes some of the initial strategies adopted in the fight against counterfeiting of regulated products, which included restructuring and reorganising NAFDAC. Staff reorientation, reorganisation and motivation were carried out to reposition employees for better effectiveness. The organisational structure I inherited was problematic. We restructured NAFDAC and created new directorates. Old laboratories were upgraded and new ones were built. Warehouses and land border offices were also constructed. New state offices, zonal offices, special inspectorate offices, and narcotic offices were established. A new corporate headquarters was acquired in Abuja to provide a conducive environment for working.

Chapter 9 describes the operational strategies employed in the war against drug counterfeiters. These strategies included development of new regulations; strict enforcement of registration guidelines; regulation and control of clinical trials; targeting the sources of counterfeit medicine and strengthening surveillance at ports of entry. We also concentrated on, the removal of fake drugs and other substandard regulated products already in circulation; monitoring the Good Manufacturing Practice (GMP) for local manufacturers; encouraging self-regulation within the

regulated industry; reviewing existing tariffs; establishment of the National Pharmacovigilance Centre; regulating access to ethical drugs strictly on prescription; developing and reviewing operational guidelines and Standard Operating Procedures (SOPs) and computerisation of the NAFDAC products registration process. We resolved conflicts resulting from disagreements between or among companies over product names, trademarks, package designs and agency rights. These modest efforts saved many companies from long years of expensive litigation. Some examples of such interventions are cited in the chapter.

Chapter 10 describes the public enlightenment campaign strategy, which involved engaging the various stakeholders in the food and drug industry in frank and open discussions. They were designed to inform consumers, thereby empowering them to exercise their rights to good quality regulated products. The public enlightenment campaigns were extended to every corner of Nigeria, involving almost everybody from religious leaders and traditional rulers to market women, rural dwellers, and students, among others. The enlightenment campaigns remain one of the most effective strategies in combating product counterfeiting and creating effective regulation.

Chapter 11 describes various ways in which employees' discipline, commitment and general positive attitude to work were inculcated and sustained. It explains how NAFDAC rewarded, encouraged and motivated those employees who made positive efforts and the sanctions it applied to those guilty of offences. They ranged from staff bonuses, training, overseas travel, enhanced salary packages, promotion when due and family-friendly working environment policies, to disciplinary measures including dismissal.

Chapter 12 highlights some of the most serious violations by local and multinational food and drug companies, and the ways in which they were handled during my tenure as Director General of NAFDAC. They are divided into five sections: drug cases, food cases, cosmetics and combined products, other general cases and litigation. They include the case of contaminated infusions produced by Biomedical Services Company Limited; contaminated *My Pikin* Baby Teething Mixture and the use of fake drugs for open heart surgery at the University of Nigeria Teaching

Hospital (UNTH). It also covers the nationwide crackdown on the importation and distribution of fake *Halfan* (halofantrine) tablets; the importation of 6,300 × 25kg bags of expired skimmed milk powder by Nestlé, the revalidation of expiry dates on chocolate bars by Cadbury and the closure of the major local drug markets: Ariaria drug market in Aba, Sabon Gari drug market in Kano, Bridgehead Market in Onitsha and Ojo Military Cantonment *mammy market* in Lagos, among others.

Chapter 13 covers the failed attempt to kill me by assassins believed to have been hired by the most powerful drug counterfeiters in Nigeria and my narrow escape from the bullets, which killed an innocent individual, followed by kidnapping attempts on my family and ferocious arson attacks against NAFDAC properties and offices throughout the country. The chapter also focuses on other factors militating against effective food and drug regulation, including corruption, inadequate legislation, sophistication in copying technology, smuggling, ignorance, poor public awareness, exploding demand and shortage of supply and poor databases on health-related activities.

Chapter 14 explains how guidelines and Standard Operating Procedures (SOPs) were developed in order to build a vibrant and sustainable institution, which would ensure uniformity in the execution of all NAFDAC regulatory functions. Guidelines and SOPs now exist for most NAFDAC activities. In addition to ensuring uniformity, the guidelines and SOPs also help to guarantee continuity in NAFDAC processes. The guidelines and SOPs are dynamic, and evolving with changes in various regulatory activities. Examples of various guidelines and SOPs are shown in this chapter.

Chapter 15 focuses on food safety. It addresses NAFDAC activities in ensuring the safety of food products in Nigeria and the role of the Agency in various international food programmes and treaties to which Nigeria is a signatory. Some of NAFDAC's activities in this regard include development of long, medium and short-term plans for improving food safety in Nigeria, staff training and development, empowering stakeholders in the food industry through workshops and seminars and establishment of a National Food Risk Analysis Centre (NFRAC).

Chapter 16 showcases some of the gains and achievements of NAFDAC between April 2001 and December 2008. Counterfeit drugs in circulation in Nigeria dropped from an average of over 41 percent in 2001 to 16.7 percent in 2006. At the time of writing this book, a NAFDAC survey indicated that counterfeit drugs in circulation had dropped to below 10 per cent. We were on the verge of commissioning another study by an international organisation to ascertain the most current level. The production capacities of local pharmaceutical industries have increased tremendously, and their number has risen steadily from 70 to 150 within the last seven and a half years. Successes in food and other sectors are also espoused, notable among which is Nigeria's rating as the first developing country to achieve universal salt iodisation.

NAFDAC received several national and international awards, notable among which are: the first recipient of the Best Consumer Sensitive Government Agency Award, from the Consumer Advocacy Forum of Nigeria (CAFON) in 2004 and the Global Anti-Counterfeiting Group (GACG) Award presented to the Agency on June 26, 2007 in Paris, at a ceremony to mark the 2007 World Anti-counterfeiting Day.

Chapter 17 discusses the support, appreciation and recognition from the Nigerian Government, Nigerians and the international community. The support NAFDAC received from the Nigerian Government was immense. NAFDAC also received lots of encouragement from the good people of Nigeria, especially the vibrant Nigerian press.

Chapter 18 covers plans for the future, recommendations and concluding thoughts on my seven and a half years' working experience in NAFDAC. Our successes in Nigeria, despite the daunting constraints, show that counterfeiters can be overcome, and that for those who dare, victory can be certain.

As I recount my years as Director General of Nigeria's National Agency for Food and Drug Administration and Control (NAFDAC), it is important to note that it is not possible to cover all that happened during this period. Time and space constraints dictate that some developments are not discussed in this book. For instance, we closed several eateries for using expired food products. There were also numerous closures of small factories and shops and various sanctions

meted on violators. We also conducted many workshops not discussed in this book. For example, the workshops for various stakeholders to sensitise the public and deter people from stealing or buying high potency Vitamin A capsules, *Coatem* and *Mectizan*, donated by the Nigerian Government, UNICEF and other donor agencies, which are meant for free distribution to the needy, and the various workshops on injection safety conducted in collaboration with John Snow Incorporated (JSI). Nevertheless, this book has captured the vision I had for NAFDAC and the mission to help eradicate counterfeit medicines in Nigeria.

ACKNOWLEDGEMENTS

My gratitude goes to Chief Olusegun Obasanjo, former President of the Federal Republic of Nigeria, who gave me the opportunity to serve as the Director General of Nigeria's National Agency for Food and Drug Administration and Control (NAFDAC), despite stiff opposition from the political class. His support in this fight for life is immeasurable. I am grateful to the late President, Alhaji Umaru Musa Yar'Adua, for continuing this support and his wife, Turai Yar'Adua, who whole-heartedly supported NAFDAC, identifying fully with the fight, just like the late wife of the former president, Mrs Stella Obasanjo. I gratefully acknowledge the contributions of Mrs Titi Abubakar, wife of former Vice President, Alhaji Atiku Abubakar; Mrs Oluremi Tinubu, wife of the former Governor of Lagos State, Asiwaju Bola Ahmed Tinubu and other government functionaries who at one time or the other encouraged my team and I.

I owe a debt of gratitude to the three Health Ministers under whom I served: Professors A.B.C. Nwosu, Eyitayo Lambo and Adenike Grange.

I thank Dr Andy Andem and Chief Ike Nwade, both past Chairmen of the Governing Council of NAFDAC and all Council members for their encouragement.

I appreciate various State Governors, traditional rulers and other government agencies, especially the Army, Police, Customs and the National Drug Law Enforcement Agency (NDLEA).

I appreciate the collaboration and support of numerous international organisations and governments including, WHO, UNICEF, IAEA, PATHS, DFID, UNDCP, INCB, USFDA, FAO, the Islamic Development Bank (IDB), the EU and the Indian Government.

In recognition of the fact that no individual achieves or performs well in isolation, I would like to acknowledge the sweat, sacrifices and tears of the hardworking NAFDAC staff, whose dedication to duty made it all possible. I particularly appreciate the various contributions made by many NAFDAC staff in the course of collating information for this book. Having commended the hardworking NAFDAC staff that made the successes possible, worthy of special mention, however, are the following individuals:

Pharmacist Dioka Ejionueme, the courageous NAFDAC Director of Enforcement. He led many successful operations but the most profound was that which led to the closure of the Onitsha bridgehead drug market. The task required a lot of intelligence, discipline and courage because Onitsha drug market is considered as the most notorious drug market in Nigeria.

Mrs Chinyere Ukaegbu, a very hardworking and courageous officer who as a Deputy Director approached me when I assumed office as the Director General of NAFDAC in April 2001 to inform me that Nestle had imported some containers of expired skimmed milk in January 2001. Encouraged by her guts, I took over the case and with her unbending stand, I was able to see it to a logical conclusion.

Pharmacist Ijeoma Nnani, an intelligent and courageous lady who led the operations of mopping-up fake products in Kano markets. It was during one of those operations that our officer, Mr Momodu, sustained multiple leg fractures. Mrs Nnani's life was so threatened that she had to sleep in different places to avoid being tracked down by the criminals. In retrospect, I feel very grateful that Mrs Nnani was posted to Kano. We needed a strong, incorruptible character like her to sanitise food and drug production and distribution in Kano. She was also the catalyst behind the establishment of the National Pharmacovigilance Centre (NPC).

Pharmacist Adeline Osakwe, who took over the Pharmacovigilance Centre from Mrs Nnani, an assignment she has continued to handle with passion. Mrs Osakwe also proposed the NAFDAC essay competition for Nigerian high school students, a catalyst for the establishment

of the NAFDAC Consumer Safety Club. The annual essay competition and the club have been institutionalised.

Mrs Jane Nzeoma, a food specialist and Deputy Director, who coordinated the entire CODEX-related activities of NAFDAC. When Jane learnt that I was writing this book, she kept insisting that I devote a chapter to documenting our many activities on food. She kept saying: “We have done so much on food that people do not recognise, because of the prominence given to drug issues.” I took her advice and that gave birth to Chapter 15, Focusing on Food.

I would like to use this opportunity to pay special condolences to the family of Mr Emeka Onuekutu, the driver of the passenger bus who was killed by the assassins’ bullets aimed at me.

The contributions of Nigerian drug manufacturers/importers, banks, various traders’ associations and other stakeholders were equally phenomenal.

The support of the vibrant Nigerian press for all NAFDAC activities was unprecedented in the history of Nigeria. The prayers of the good people of Nigeria in Churches and Mosques across the country was our source of strength

I thank my very good friend Mrs Kate Isa for her friendship, support and contributions to the writing of this book.

My deepest appreciation and love go to the six apples of my eye: Ijeoma, Edozie, Somto, Njideka, Chidiogo and Obumneme, and to my husband, Dr Chike Akunyili – thank you very much for your wonderful support.

Above all, I am most grateful to God who graciously protected me, making it possible for me to live to tell this story.

Dora N. Akunyili, PhD, OFR, FPSN

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PROLOGUE

MY LIFE WAS PREPARED AND PRESERVED FOR THIS JOB

As a child, I never thought of studying pharmacy. In the early 1970s in Nigeria, medicine and law were popular career choices for young people aspiring to enter a university for higher education. It was the vogue for students with excellent West African School Certificate (WASC) results in the sciences to study medicine. As a science major, my first choice was medicine, and that was what my family desired for me. I performed very well in the WASC examination and passed with a Grade One distinction. However, there was a problem as far as I was concerned, the curriculum for medicine had very little mathematics and chemistry, which were my favourite subjects. I had briefly considered studying mathematics as single honours but soon discarded the idea. Nevertheless, I still yearned for a course that would give me the opportunity to continue with mathematics and chemistry. This was how I chose pharmacy, a course that prepared me for the journey that led me to the position of the Director General of Nigeria's National Agency for Food and Drug Administration and Control (NAFDAC). The law that set up NAFDAC states that the Director General “...*shall be a person with good knowledge of pharmacy, food and drugs*”.

At the end of my first year in the University of Nigeria Nsukka (UNN), I was at the top of my class and won the Kingsway Prize for the best first year student. Once more, I was pressured to change over to medicine. Grudgingly, I agreed and approached Prof. James Ezeilo, the then Vice-Chancellor of the UNN, who gave me a note to the Dean of the College of Medicine, Prof. Udekwu. On reading the note, Prof. Udekwu exclaimed: “In the whole medical school, there is only one first year result that is as good as yours but unfortunately, admissions for transfers have closed.” However, with my outstanding performance and the weight of Prof. Ezeilo's note, he

resolved to give me a chance. “Come on Friday,” he said. “Let’s see what can be done.” I never went back to see him, and I had no good reason for not doing so.

Life in the Village

I was born on July 14, 1954 in Makurdi, a city in the northern part of Nigeria, to Chief Paul Young Edemobi and Mrs Grace Udemehie Edemobi both deceased. My father was a very successful businessman, contractor and an influential politician. He built most of the government facilities in Makurdi in the 1950s and 1960s. He was also the conservancy contractor for the whole province. My father was so wealthy that in the early 1960s he used to charter an aircraft to travel from Kano to Makurdi. He was a philanthropist and sponsored academic education or vocational training for most of his kin.

Life in Makurdi was beautiful. We lived in the upper-middle-class area of the city. As a little girl, I was always at the top of my class. Due to my performance in school, my father exempted me from all household chores, insisting that I should not be distracted from my studies. His popular saying was: “Dora’s brain will earn her cooks and stewards.” This favouritism did not go down well with my mother and my siblings. They became very uncomfortable, fearing that I would end up being a spoilt child. Consequently, they “conspired” and convinced my father to send me to Isuofia, a village in the south-eastern part of Nigeria, to live with my maternal grandmother, Mrs Mgbeke Lucy Okoli, and my uncle, Mr Romanus Okoli, a renowned village teacher. My father, believing that teachers were the best at training children, succumbed to the conspiracy. In December 1963, when I was a little over nine, I was whisked off to the village to start a new life. It was a culture shock to me.

Growing up in Isuofia was very difficult for me. The village was devoid of all basic social amenities like potable water, electricity and toilet facilities. Children in the cities were better off because they had access to basic modern facilities. Those born and brought up in the village did not know any better and so did not feel the loss. It was, however, hard for a child like me who started life in the city, in comparative luxury, to adjust. I used to cry every day until I got used to village life.

I attended primary 4 to 6 in the village. A typical day started at dawn, when I had to trek for miles to fetch water from the stream, navigating through winding, narrow, slippery and risky paths, ravaged by gully erosion. At this time of the day, the path was pitch dark, with occasional streaks of moonlight for illumination. On some occasions, I would come back from the stream frustrated and in tears, without water, having stumbled along the rough terrain and broken my clay pot. Grandmother believed that it was an unnecessary luxury to use metal or plastic buckets to fetch water. One early morning, I could have fallen into a big gully but for the timely intervention of an elderly woman who was walking behind me. Thick and dark clouds blanketed the little illumination from the moon as we set out for the stream. My tiny legs grew tired and heavy; sleep hung heavily on my eyelids. I was deep in an early morning reverie when a loud scream pierced the air. Before I could make out what was happening, a firm hand clutched my shoulder and yanked me rather violently out of danger. If not for the swiftness of the woman, I would have plunged into the deep ravine on the side of the path. It was a very frightening experience. However, not even this horrifying experience could earn me a respite from the early morning water-fetching chore.

On occasions when we had enough water at home, I would go to work on my grandmother's farm. I returned home in the early hours of the morning to sweep the compound and my grandmother's small house. Thereafter, I warmed and ate the cassava *fufu* that was left over from the previous night, washed my face, hands and legs and trekked about a mile to school. If I got to school a minute after resumption time, my teacher, who never bothered to find out why I was late, would flog me mercilessly. My uncle, who was a teacher in the school, did not protect me in any way, because he believed it was part of the training. After the close of school, I would trek home, cook yam and eat it with palm oil, or vegetables during the vegetable season. We only ate rice on Sunday afternoons, as a luxury.

Immediately after lunch, I would go to the bush to fetch firewood. If we had enough firewood, I would go to the farm to weed, plant or harvest crops, depending on the season. We usually left the farm at sunset. On getting home, we would either make soup or warm an old pot of soup and prepare cassava *fufu* for dinner. Thereafter, I would do all the cleaning up before doing my

homework on a rickety table with a smoky lantern, after which I would go to sleep on a raffia mat placed on a cement floor. My parents had actually sent a camp bed to ensure that I was comfortable, but the driver who brought it did not explain what it was meant for. It was folded and never used until I fell ill with severe pneumonia, which nearly took my life. We subsequently learnt that the folded thing in the corner of the room was actually a camp bed. A driver had to be sent from Makurdi, an eight-hour drive, to set it up. That was how I started sleeping on the camp bed for the rest of my stay in the village.

Of all my chores, the one I disliked the most was going to the forest to fetch firewood. We had to trek long distances, through farmlands and forest, to get to suitable sites to fetch the firewood. The sun beat down on us so mercilessly that my clothes clung to my skin from profuse sweat. Twigs scratched my arms and legs. The walk home with the firewood precariously perched on my head was even more arduous. Negotiating tree stumps, shrubs and twigs with the firewood was not an easy feat. Watching out for snakes, and other dangerous reptiles, made this journey more harrowing. In the village, there was never a dull moment. My grandmother regarded any form of rest as laziness. This life pattern has so influenced me that now, I find it very difficult to rest.

I worked very hard at school because I desperately wanted to get away from the village, and I knew that the only way to escape was to gain admission to one of the top government high schools. In 1967, I passed my first school-leaving certificate with a distinction, which earned me the Eastern Nigerian Post Primary Scholarship.

Today, I have absolutely no regrets about the hardship I suffered in the village. It trained me to be strong and resilient, able to adapt to any situation, no matter how harsh. I also imbibed a culture of contentment and zero tolerance for corruption. This is because in our traditional village setting, corruption was completely unacceptable. It was a taboo, which destroyed both the culprit and his or her lineage. In fact, there is no direct translation for the word corruption in my native language – Igbo. Families endeavoured to maintain their integrity, as people were ostracised for

stealing, embezzling community funds or cheating. The children of such people could neither marry nor be married in the village. Furthermore, people who stole from their communities were barred from taking any chieftaincy title, and the story was passed on from one generation to the next. For example, grandmother barred me from associating with a classmate of mine whose grandfather (who died before she was born) had stolen tubers of yam. My grandmother always said that stealing ran in their blood. This brilliant child, whom I very much wanted as a friend, was branded *Nnwa onye ori* (child of a thief). The stigma was much more of a deterrent to theft than any modern-day sanction.

With the outbreak of the Nigerian Civil War of 1967–70, my siblings in the city were forced to return to our village, Nanka, and I became something of a local champion, teaching them the village way of life. In the face of hunger, air raids by jet bombers and other vicissitudes of the war, I decided to enroll in a school in Agulu, many miles away from my village, in order to continue with my high school education. I was determined to succeed in life through academic excellence. I used to leave home well before 5am to get to school before 8am. I went to school without breakfast because there was so much hunger, starvation and suffering in Biafra, our side in the war. I only had my little share of food to eat when I came back from school late in the evening. I still have nightmares when I remember the hunger pangs of the war period. I watched the skin of some of my school mates gradually change from shades of brown to pale and translucent, and their hair turn light and curly due to the onset of *kwashiorkor*, a starvation-induced illness.

On some occasions, along the road to school, the sound of jet bombers would split the air. Shouts of *take cover* would be heard all around, and we would dive into the bush and hide under trees, to avoid being seen by the jet bomber pilots who sprayed bullets whenever they saw movement. Sometimes we came out from the bush to see heavy casualties of dead or mutilated bodies. In the face of these dangers, I was resolute to succeed. My mother used to queue up every week to get our weekly ration of food from Caritas, a German religious organisation. My father would usually give me part of his ration, saying that he would rather die than lose his Dora.

One experience of the war, which hurts very deeply whenever I remember it, is that of being exploited and used as unpaid child-labourer. In early 1969, Nigerian soldiers over-ran the village where my school was and were advancing towards my village. Luckily, the occupation happened at night, and we were spared being raped or killed while in school. My parents felt that it was not wise for us to continue to live in Nanka, as it appeared to be the next target for the advancing Nigerian soldiers. We relocated to Umulolo village, near Okigwe town, where my parents ran a small restaurant. When we heard that labourers of all ages were required in a nearby agricultural farm at Ikpa Ora for cultivation of onions and other cash crops, my two elder sisters and I went and we were immediately enrolled as labourers. The salary promised was attractive and my parents were happy that relief would come from there. We worked all day, from Monday to Friday, under the heat of the sun, and were only allowed to go under big trees for cover when the rain was heavy. Months passed by and Mr Nwokabia, the farm manager, continued to promise to pay us our accumulated salaries the following day. We kept working, hoping and praying that we would get paid some day, but pay day never came. When Okigwe was over-run by the Nigerian army, Umulolo appeared to be the next target. The deafening bangs of shelling hitting the once peaceful village, forced us to abandon our new home, restaurant and everything. With the war raging all around us, we trekked for two days, covering many miles, to return to Nanka. My parents believed that if we were going to be killed in the war, it was better to die in our village than elsewhere.

After the war, our whole family left for Enugu, in the south-east, instead of going back to Makurdi where my parents had lived for most of their lives. I went back to school. The schools had been vandalized and had no windows, no doors, no desks, no water and very little food. However, I was able to cope since I was used to harsher conditions, and besides, I was so desperate to attend school that I was ready to contend with any situation. I worked hard and graduated in 1973 with a Grade I distinction, which earned me the Federal Government Undergraduate Scholarship for my university education. After graduation from the university, I worked for a

while in a hospital, before proceeding to postgraduate studies, for which I was offered a direct PhD programme in the University of Nigeria, Nsukka, again on scholarship and with full pay, as a graduate assistant. Even though I was married and having babies, I continued to work hard. Hard work had become an integral part of me.

My experience in the village taught me that we have geniuses languishing in ignorance and poverty, whose talents are never developed, and who may never have the opportunity to develop their potential. A singular encounter with Godwin, one of my classmates in the village, many years after we left school, made me to be appreciative of the opportunities I have had in life. Godwin is one of the most intelligent people I have ever met. From primary 4 to 6, he was my fiercest competitor. He was the only pupil who competed with me for the first position in examinations. I needed to work extra hard to match or beat him. When I met Godwin again in 1975, while in my third year at university, he was a motor park attendant. Motor park attendants assist bus drivers to find passengers for their vehicles. There are many Godwins in Nigeria, and indeed other developing countries, who never get the opportunity to realise their full potential.

My Journey into Public Service

After my PhD, I started teaching at the University of Nigeria Nsukka (UNN), and my greatest dream was to become a professor. I was not interested in politics or political positions, but I desperately wanted to help the poor people around us in my husband's village. Consequently, whenever my husband, a medical doctor, went home at weekends to provide free medical services to the poor, I went along to assist him.

During these visits, I discovered that there was no health facility anywhere in the village. I was determined to find a way to raise funds to build a hospital for them. I discussed this with my husband, and he was in full support. There was an old abandoned, dilapidated building that was supposed to have been a hospital, but it had never materialised. I went to the women's meeting in the village and talked to them about the need for us to contribute money to refurbish the

building. They were happy with this suggestion and expressed their readiness to cooperate with me to achieve this. In less than six months, the building was renovated.

The next challenge was how to equip the hospital. I felt it was time to approach the men, because this phase of the project was more capital intensive. Consequently, I attended the men's meeting and solicited their help in equipping the hospital.

On my way to the men's meeting, I was contemplating how to introduce my plan. Just before I started to address them, it occurred to me that, since they did not know me well enough to vouch for my integrity, they might not be well disposed to contributing cash for the project. I therefore decided not to ask for cash but to request that they volunteer, as individuals or families, to equip the wards, clinics, theatres and other parts of the hospital. Each person or family who equipped any part of the hospital would have that area named after them. In this way, their names would be immortalised and future generations would know the part they played in providing the health facility for the village. I played on how hard the women had worked to contribute money towards the renovation of the hospital. The men jumped at the idea, and in under an hour we had pledges to fund the equipment for every part of the hospital. They were as excited as the women. They were all pleasantly surprised that a non-Agulu indigene could be so interested in the welfare of their community.

Furthermore, the fact that I did not ask them for money allayed any scepticism associated with such professed selfless ventures.

The town leaders told the State Commissioner of Health, Prof. A.B.C. Nwosu, about the project, and he was so impressed that he also donated some hospital equipment. In less than six months, the hospital was ready.

Shortly afterwards, the Governor of my State, Anambra in south-eastern Nigeria, asked the leaders of my husband's village, led by Chief Dan Ogbuefi, to nominate one person for a political appointment by the new administration. They unanimously nominated me, and thus I started my career in public service as a member of the Caretaker Committee of our Local Government

Area, where I worked from 1994 to 1996. Around the same time, the Governor asked for another nomination for appointment to the board of relevant state agencies. My name was again the only one submitted by the village leaders. Consequently, I was appointed a member of the State Hospitals Management Board, the State Advisory Council for Women Commission and the State Coordinator of the Better Life for Rural Women Programme.

While carrying out these responsibilities, I was then interviewed for, and appointed as, the Zonal Secretary of the Petroleum (Special) Trust Fund (PTF), another political position. PTF was set up by the then military administration as an intervention agency for the provision of social infrastructure in Nigeria.

Between 1997 and 2000, I served as the Zonal Secretary of the PTF where I coordinated all projects in the five south-eastern states of Nigeria. While at the PTF, I was diagnosed with a suspected pancreatic problem and travelled to London for treatment. I was given £17,000 by the PTF, from which I was supposed to pay £12,000 for surgery and £5,000 for other expenses. Fortunately, after several tests, the doctors in London found that the initial diagnosis was wrong, and that I did not require surgery. The hospital refunded the £12,000.

On my return to Nigeria, I wrote a letter of appreciation to the Executive Chairman of the PTF, a former Nigerian Head of State, Major General Muhammadu Buhari (rtd), and returned the £12,000. General Buhari wrote a commendation for this action (Appendix 1). He told my story to his friend, Dr Onalapo Soley, a former Minister of Finance in Nigeria.

Just about that time, the activities of the PTF were winding up, and I visited the headquarters at Abuja to see one of my colleagues, Engr. Toyin Jokosenumi. As I walked into his office, he turned to a middle-aged man seated beside him and said: “Daddy, this is the woman who returned the £12,000.” The man, who turned out to be Dr Soley, was impressed and told me that his friend, Mr President, Chief Olusegun Obasanjo, was looking for somebody to clean up NAFDAC, and being a pharmacist, I was qualified for the position. He asked for my CV. I was a bit

confused. I did not know much about NAFDAC, and besides, I did not have a copy of my CV with me. He asked me to go and produce a typed copy. I did.

On a Sunday afternoon soon afterwards, I got a phone call and my heart skipped a beat when I heard: “My name is Obasanjo.” I nearly collapsed! I was confused. I still cannot quite remember what I said next. I went to see him in Abuja the following week. This very kind and fatherly man asked about the money that I returned, and other general questions.

I was neither an active politician nor a member of the President’s party, and I did not have a political “godfather”, so the President faced some stiff opposition to my appointment. The strongest complaint was that it was inappropriate to make an Igbo person the Director General of NAFDAC, while the Health Minister, Prof. A.B.C. Nwosu, is Igbo, and most drug counterfeiters are Igbos. Ethnicity is a major consideration in Nigerian politics and governance. Gender was also an issue.

When the news of my appointment was made public, some people complained that I had no experience of government work. They were right. They also thought that at 47, I was too young for the job. Some argued that I might not have the capacity to tackle the hydra-headed monster called counterfeit medicines. On this point, they were wrong. Knowing my limitations, I ran to God, in the presence of the Blessed Sacrament of the altar, and cried, saying:

“Lord, I have no experience, I don’t even fully understand the functions of NAFDAC, but God, You are experience Yourself. I am young but You are ageless. I have no capacity, but God of impossibilities, You are capable. Use me mightily as a vessel to perform this seemingly impossible task of eradicating counterfeit medicines from Nigeria, despite my limitations. It is only You that can use a crooked pen to write on a straight line.”

On that day, I made a covenant with God that I would do my very best to bring Him Glory on the job, and that if I should ever compromise with drug counterfeiters, He should strike me dead. God has been faithful to me, and I continue to seek His Grace to keep my part of this covenant. In the face of obstacles, trials, temptations, assassination attempts and arson, I always recall my pledge to God.

CHAPTER 1

EVOLUTION OF DRUG PRODUCTION AND SALE IN NIGERIA

The development of pharmaceuticals in Nigeria has undergone significant evolution, from the concoctions infused from cocktails of leaves, fruits, barks and roots, to conventional Western medicine. Traditional remedies are still widely used, especially by the poor.

The pharmaceutical industry in Nigeria has passed through a tortuous path: from the rudimentary era of pre-1957; through the foundation-laying era of the 1960s and the oil boom era of the 1970s; to the harrowing experience of the Structural Adjustment Programme (SAP), which was recommended by the International Monetary Fund (IMF); to the period of unfair competition with drug counterfeiters of the 1980s and 1990s; and presently into the potentially bright post-2001 era.

Phase I (Pre-1957 Era)

The first phase began with the establishment of the first pharmacy in Lagos, Nigeria, by Dr Zacheus Bailey.¹ During this time, pharmaceutical business involved the distribution of imported drugs by representatives of different multinational pharmaceutical companies. These include Beecham, May & Baker, Pfizer, Glaxo and J.L. Morrison. There was no local manufacturing of Western medicine in Nigeria before 1957.

Phase II (1957–1977)

This phase covered the period when multinational pharmaceutical companies started drug production in Nigeria. They include Glaxo (1958), Pfizer (1962), Sterling (1963), Wellcome (1967), PZ (1968), Pharchem (1968), SmithKline Beecham (1973) and May & Baker (1977). At the end of the Nigerian Civil War in 1970, the oil boom era emerged. This was a bright time for the drug companies and the Nigerian economy in general, as profits, employment and foreign exchange remittance swelled. However, the pharmaceutical companies were solely owned and operated by foreigners, with no indigenous participation.

Phase III (1978–1982)

The enactment of the Indigenisation Policy in 1978 ushered in the third phase. The policy compelled most of the multinational companies to sell 60 per cent of their shares to Nigerian investors, although some multinationals, such as Hoechst (1982) continued to come into Nigeria. This was also the period when indigenous drug companies emerged. They include Biode, Rajrab and Pharmaceuticals Pharma in 1980, and Biomedical Services in 1981. The Federal Government and the then Bendel State Government also set up drug manufacturing facilities, which produced oral and topical medications.

Phase IV (1983–1986)

The Federal Government introduced the use of import licence for all imported goods, including drugs. This altered the course of history and the development of the pharmaceutical industry in Nigeria. Import licences were granted based on political patronage. Many people who had no business with pharmaceutical products obtained the licences, while most pharmacists, drug manufacturers and genuine importers were denied access to the greatly needed foreign exchange at official rates. They were subsequently forced to re-purchase the import licences at exorbitant rates from those people whose factories and offices were located in their briefcases. This unfair issuance of import licences created havoc, resulting in the flooding of Nigerian markets with all sorts of fake/counterfeit drugs and other substandard health sensitive products. The Nigerian Government's implementation of SAP as recommended by the IMF, further exacerbated the decline of the fragile pharmaceutical industry. Even in the face of this chaos, more indigenous pharmaceutical manufacturers, such as Emzor, Mopson, Barewa, Geonnasons, Continental, Ashmina and Afrik were established.

Phase V (1987– 2001)

During this period, drug counterfeiters who had been importing counterfeit medicines into Nigeria since the late 1960s started displacing the genuine producers and importers, as the counterfeits were cheaper than the genuine drugs. This unfair competition crippled the existing 70 local drug manufacturers, and many multinational companies left Nigeria out of frustration. Furthermore, most West African countries banned Made-in-Nigeria drugs.

Phase VI (2001–2008)

This was the era of revival, which ushered in hope for the Nigerian pharmaceutical industry. At this point, we declared an all out-war against drug counterfeiters, which led to the

sanitisation of the drug industry, resulting in increased capacity utilisation, and subsequent expansion in production capacities. Presently, there are 150 local pharmaceutical manufacturing companies producing over 40 per cent of Nigeria's drug need. The Nigerian Government abolished Value Added Tax (VAT) on pharmaceutical raw materials, and reduced import tariffs for raw materials and equipment for drug production as incentives for the pharmaceutical industry, and this has greatly encouraged them.

The ownership structure of the pharmaceutical industry in Nigeria as of December 2008 is as follows: Indigenous manufacturers— 58 per cent; Asian-owned – 18 per cent; Anglo-American-owned – 14 per cent; Government-owned – 5 per cent and others – 5 per cent.

CHAPTER 2

EVOLUTION OF FOOD AND DRUG REGULATION IN NIGERIA

Throughout history, society has been concerned with the quality of drugs, food and other health sensitive products. This prompted several societies to undertake some kind of regulation for the production and use of such products. For instance, in ancient Egypt, during the first century BC, physicians were required to administer their drugs in accordance with written laws. If they failed to do so in any respect and the patient died, they were tried and punished. During the first century AD, methods were also designed to counteract the problem of drug adulteration.

The origin of the United States Food and Drug Administration (USFDA) dates back to June 1906, when President Teddy Roosevelt signed the Food and Drugs Act and entrusted the implementation of this law to the Bureau of Chemistry of the US Department of Agriculture. The Bureau, which is the oldest US consumer protection office, eventually became the Food and Drug Administration (FDA), an Agency of the Department of Health and Human Services. The FDA was further strengthened by the 1938 Federal Food, Drug and Cosmetic Act, which became necessary after the Sulfanilamide elixir tragedy. Since then, other countries, at various times, have followed the example of the USA to establish their own drug regulatory agencies.

Historical Development of Food and Drug Regulation in Nigeria

The regulation and control of food and drugs in Nigeria has a chequered and beleaguered history. The first known legislation in this area was the 1891 Sale of Drug Ordinance. This law was made to apply to the then colony of Lagos. It was later repealed and re-enacted in 1902. The ordinance was subsequently extended to the Colony and Protectorate of Southern and Northern Nigeria in 1907. A nationwide Drugs and Poisons Ordinance was promulgated in 1915, following the amalgamation of Northern and Southern Nigeria in 1914. This statute went through some amendments, repeals and re-enactments in 1922, 1927 and 1936. The Pharmacy Ordinance of 1945 repealed the 1936 legislation. In 1964, it was renamed the

Poisons and Pharmacy Act. The main thrust of this Act was to ensure the controlled sale and use of certain drugs and poisons.

7

In the case of food regulation, the first known legislation was the Food Adulteration Ordinance of 1903. It applied to the then Colony of Lagos. With the 1914 amalgamation, the 1903 law was repealed by the Sale of Food Ordinance of 1917, which took effect in 1954 as regional legislation, due to the adoption of a federal structure for the country. This law was replaced with the Food and Drug Act of 1974. As in the case of drugs and poisons, the policy thrust was geared towards prohibition, as against proper regulation.

Initial Attempt at an Institutional Framework

The first attempt at providing a modern institutional framework for the regulation of food and drugs in Nigeria was in 1974, with the Food and Drugs Decree (now Act). This was to regulate the manufacture, sale and advertisement of food, drugs, cosmetics and medical devices. With the promulgation of the Act, the Directorate of Food and Drug Administration and Control (FDAC) was established in the Federal Ministry of Health, to enforce the provisions of the legislation. In FDAC, there were quality control laboratories, provision for inspection and enforcement, and a fairly well-equipped drug-manufacturing laboratory. However, there was no provision for product registration, thereby making drug importation and manufacturing a free-for-all affair. Civil service bureaucracy, corruption, political instability and a host of other lapses hindered the activities of FDAC. To remove the bottlenecks in FDAC, and ensure effectiveness, NAFDAC was established in 1993 by the then Nigerian Head of State, General Ibrahim Badamasi Babangida. The Minister of Health at the time was the late Prof. Olikoye Ransome-Kuti.

CHAPTER 3

NAFDAC MANDATE, STRUCTURE, FUNCTIONS, LAWS AND REGULATIONS

NAFDAC Mandate

NAFDAC is a parastatal under the Federal Ministry of Health. It was established by Decree No. 15 of 1993, to regulate and control the manufacture, importation, exportation, advertisement, distribution, sale and use of food, drugs, medical devices, cosmetics, detergents, chemicals and all packaged drinks. NAFDAC, therefore, has a statutory responsibility to ensure the quality, safety and efficacy of these items, collectively referred to as regulated products.

NAFDAC Structure

A Chief Executive Officer (CEO) addressed as the Director General, who reports to the Governing Council, heads NAFDAC. The Council is made up of representatives from the food and drug industry, the Federal Ministry of Health, the Standards Organisation of Nigeria (SON), the National Institute for Pharmaceutical Research and Development (NIPRD), the National Drug Law Enforcement Agency (NDLEA), and four members of the public, one of whom serves as the Chairman of the Council. The Council meets at least once every quarter to deliberate on policy issues. The Director General is in charge of the day-to-day running of the Agency. Before my appointment in 2001, NAFDAC had six Directorates namely: Administration & Finance; Registration & Regulatory Affairs; Inspectorate; Laboratory Services; Narcotics; and Planning, Research & Statistics. A Director, who reports to the Director General, heads each Directorate. In addition to the Corporate Headquarters located in Abuja and an Operational Headquarters in Lagos, NAFDAC also had 24 state offices and four laboratory complexes. The Organisational Structure of NAFDAC is depicted in the chart shown in Figure 1.

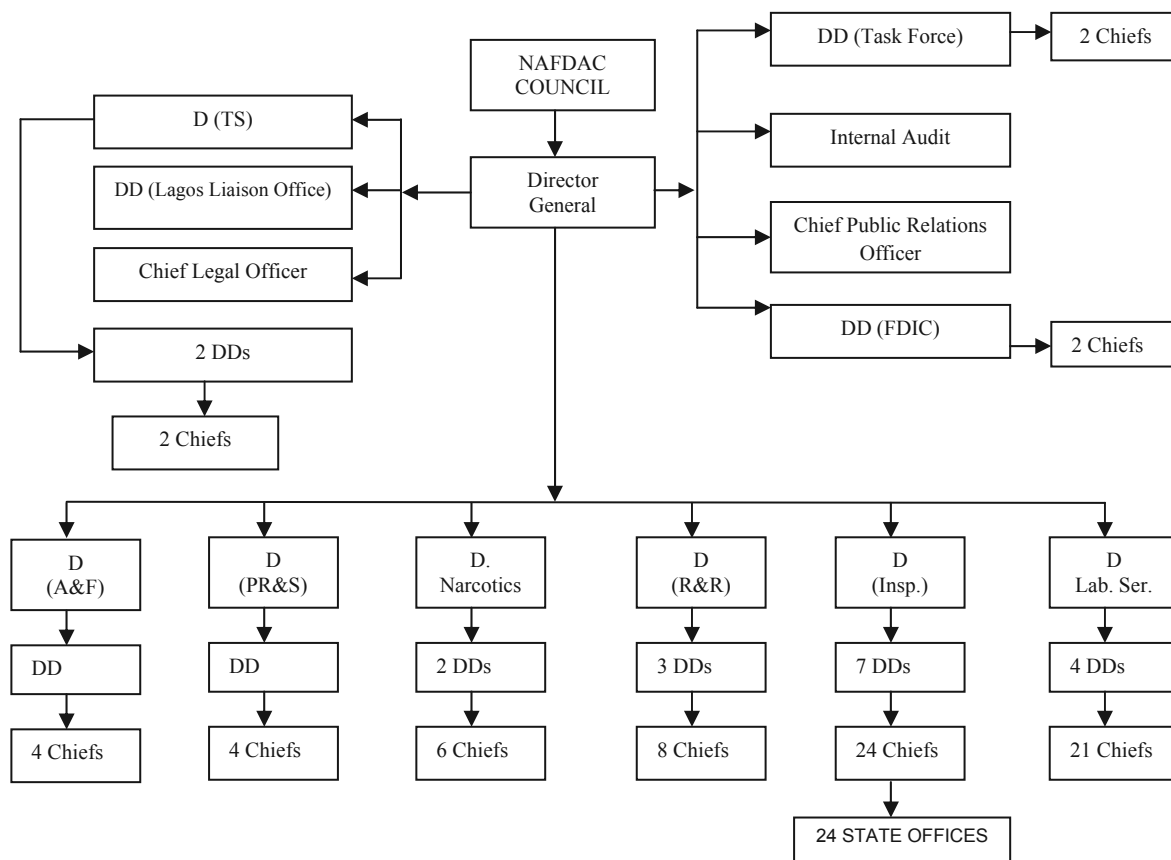


Figure 1: NAFDAC Organisational Chart before April 2001

Key: D – Director; DD – Deputy Director; A&F – Administration and Finance; PR&S – Planning, Research and Statistics; R&R – Registration and Regulatory Affairs; Insp.– Inspectorate; Lab. Ser. – Laboratory Services; TS – Technical Services.

Functions of NAFDAC

NAFDAC's functions, as provided in Section 5 of Decree 15, 1993, are:

- i. To regulate and control the importation, exportation, manufacture, advertisement, distribution, sale and use of food, drugs, cosmetics, medical devices, bottled water and chemicals.
- ii. To conduct appropriate tests and ensure compliance with standard specifications designated and approved by NAFDAC's Governing Council, for the effective control of the quality of food, drugs, cosmetics, medical devices, bottled water and chemicals, and their raw materials, as well as their production processes in factories and other establishments.

- iii. To undertake appropriate investigations into the production premises, and raw materials for food, drugs, cosmetics, medical devices, bottled water and chemicals, and establish relevant quality assurance systems, including certification of the production sites, and the regulated products.
- iv. To undertake inspection of imported food, drugs, cosmetics, medical devices, bottled water and chemicals, and establish relevant quality assurance systems, including certification of the production sites, and the regulated products.
- v. To compile standard specifications and guidelines for the production, importation, exportation, sale and distribution of food, drugs, cosmetics, medical devices, bottled water and chemicals.
- vi. To undertake the registration of food, drugs, cosmetics, medical devices, bottled water and chemicals.
- vii. To control the exportation, and issue quality certification for food, drugs, cosmetics, medical devices, bottled water and chemicals intended for export.
- viii. To establish and maintain relevant laboratories.
- ix. To pronounce on the quality and safety of foods, drugs, cosmetics, medical devices, bottled water and chemicals, after appropriate analysis.
- x. To ensure that the use of narcotic drugs and psychotropic substances are limited to medical and scientific purposes.
- xi. To grant authorisation for the import and export of narcotic drugs and psychotropic substances, as well as other controlled substances.
- xii. To collaborate with the National Drug Law Enforcement Agency (NDLEA) on measures to eradicate drug abuse in Nigeria.
- xiii. To advise Federal, State and Local Governments, the private sector and other interested bodies regarding the quality, safety and regulatory provisions on food, drugs, cosmetics, medical devices, bottled water and chemicals.
- xiv. To undertake and coordinate research programmes on the storage, administration, distribution and rational use of food, drugs, cosmetics, medical devices, bottled water and chemicals.

- xv. To issue guidelines on, approve and monitor the advertisement of food, drugs, cosmetics, medical devices, bottled water and chemicals.
- xvi. To compile and publish relevant data resulting from the performance of functions of the Agency under this Decree or from other sources.
- xvii. To sponsor such national and international conferences as it may consider appropriate.
- xviii. To liaise with relevant establishments within, and outside Nigeria in the pursuance of the functions of the Agency.
- xix. To determine the suitability or otherwise of food, drugs, cosmetics, medical devices, bottled water and chemicals for human and animal use, and
- xx. To carry out such other activities as are necessary or expedient for the performance of its functions under this Decree.

Laws by which NAFDAC Operates

From 1993 when NAFDAC was established, it started to exercise some level of autonomy. This, coupled with increased operational activities, made it necessary for the enactment of laws to support the Agency's work, which gave rise to several Federal Decrees in the 1990s.

One of the most effective laws and some of its highlights are as follows:

Counterfeit and Fake drugs and Unwholesome Processed Foods (Miscellaneous Provisions) Decree No. 25 of 1999, which repealed the Counterfeit and Fake drugs (Miscellaneous Provisions) Decree No. 17 of 1989. This was the most effective law in terms of deterrence. Under this law, a convict may be asked to pay a maximum fine of ₦500,000 (US\$4,348), or serve a prison sentence of between 5 and 15 years. In addition to the principal offenders, it targets persons who aid or abet the crime, and provides that if convicted, they be fined not more than ₦500,000 (US\$4,348), or be sentenced to a term of imprisonment not exceeding two years. This is a great improvement from the provisions of the repealed law, which stipulated that such a class of offenders could not be fined more than ₦5,000 (US\$43). The law also provides that the convict forfeits the offending products to the government.

The laws governing NAFDAC are captured in Appendix 2.

The laws governing the operations of NAFDAC empower the Agency to make regulations, as and when needed, for greater effectiveness. This entails the compilation of technical details and scientific standards for all regulated products, in order to ensure the safety of the products. Regulations may also be used to fill in gaps in the principal laws.

Fourteen regulations were gazetted by NAFDAC between 1993 and April 2001, a full list of which is contained in Appendix 3.

CHAPTER 4

DEFINITIONS: FAKE / COUNTERFEIT / ADULTERATED / SUBSTANDARD DRUGS, UNWHOLESOME FOOD AND OTHER SUBSTANDARD REGULATED PRODUCTS

Fake and Counterfeit Drugs

Despite the global nature of fake and counterfeit drugs, the international community has not given the problem the attention it deserves, as evidenced by it not having a harmonised definition. Consequently, various countries and organisations have different definitions, according to their perception of the problem. The absence of a universally accepted definition not only makes information exchange between countries difficult, but also limits the ability to understand the scope of the problem.

According to Black's Law Dictionary, the term counterfeit drug may be used to describe a drug produced by an entity other than the genuine manufacturer, by copying or imitating an original product without authority or right, with a view to deceiving or defrauding the consuming public, and then offering for sale the copied or forged drug as the original.²

The World Health Organization (WHO), defines a counterfeit medicine as “one which is deliberately and fraudulently mislabelled with respect to identity and/or source. Counterfeiting can apply to both branded and generic products, and counterfeit products may include products with the correct ingredients or with the wrong ingredients, without active ingredients, with insufficient active ingredients or with fake packaging”.³

The United States Federal Food, Drug and Cosmetic Act defines a counterfeit drug as, “a drug which, or the containers or labelling of which, without authorization, bears the trademark, trade name, or other identifying mark, imprint, or any likeness thereof, of a drug manufacturer, processor, packer, or distributor, other than the person or persons who, in fact, manufactured, processed, packed, or distributed such drugs, and which, thereby, falsely purports or is represented to be the product of, or to have been packed or distributed by, such other drug manufacturer, processor, packer or distributor”.⁴

International Pharmaceutical Federation (FIP) defines counterfeit medicines as medicinal products that have been deliberately or fraudulently mislabelled with respect to their identity, composition and/or source. These include those products with the correct ingredients, wrong ingredients, no active ingredient, or fake packaging.⁵ This definition excluded substandard products which were correctly labelled.

In Pakistan's Manual of Drug Laws, a counterfeit drug is defined as "a drug, the label or outer packing of which, is an imitation of, resembles or so resembles as to be calculated to deceive, the label or outer packing of a drug manufacturer".⁶ In the Philippines, the Republic Act No.82036 refers to counterfeit drug/medicine to mean: "...medicinal products with correct ingredients but not in the amounts as provided thereunder, wrong ingredients, without active ingredients, with insufficient quantity of active ingredients, which results in the reduction of the drug's safety, efficacy, quality, strength or purity. It is a drug, which is deliberately and fraudulently mislabelled with respect to identity and/or source, or with fake packaging, and can apply to both branded and generic products. It shall also refer to:

1. The drug itself, or the container or labelling thereof, or any part of such drug, container or labelling bearing without authorisation, the trademark, trade name or other identification mark or imprint or any likeness to that which is owned or registered in the Bureau of Patent, Trademark, and Technology Transfer, in the name of another natural or juridiciary person;
2. A drug product refilled in containers by unauthorised persons if the legitimate labels or marks are used;
3. An unregistered imported drug product, except drugs brought into the country for personal use as confirmed and justified by accompanying medical records, and
4. A drug which contains no amount of, or a different active ingredient, or less than 80 per cent of the active ingredient it purports to possess, as distinguished from an adulterated drug, including reduction or loss of efficacy due to expiration."⁷

Nigerian Definitions

The Nigerian definition combines the provisions of two decrees: The Drugs and Related Products (Registration) Decree No. 19 of 1993⁸ and the Counterfeit and Counterfeit medicines and Unwholesome Processed Foods (Miscellaneous Provisions) Decree No. 25 of 1999.⁹

Counterfeit Medicines

By Nigerian law, a counterfeit drug, also referred to as a fake drug, is defined as:

- (a) Any drug or drug product, which is not what it purports to be.
- (b) Any drug or drug product which is so coloured, coated, powdered or polished, that the damage is concealed, or which is made to appear to be better or of greater therapeutic value than it really is, or which is not labelled in the prescribed manner, or which label or container or anything accompanying the drug bears any statement, design or device which makes a false claim for the drug, or which is false or misleading.
- (c) Any drug or drug product whose container is so made, formed or filled as to be misleading.
- (d) Any drug or drug product whose label does not bear adequate directions for use and such adequate warning for use in those pathological conditions or by children where its use may be dangerous to health, or against unsafe dosage or methods or duration of use, or
- (e) Any drug or drug product, which is not registered by NAFDAC in accordance with the provisions of the Food, Drugs and Related Products (Registration, etc.) Decree, 1993, as amended.

Adulterated Drugs

Nigerian law describes a drug as adulterated if:

- (a) The methods used in, or the facilities or controls used for its manufacture, processing, packing, or holding do not conform to, or are not operated or administered in conformity with current Good Manufacturing Practice (GMP), to assure that such drugs meet the requirements of the Food and Drugs Act as to their safety and has the identity and strength and meets the quality and purity characteristics which it purports or is represented to possess.
- (b) It purports to be or is represented as a drug, the name of which is recognised in an official compendium, has its strength differing from, or its quality or purity falling below the standard set forth in such compendium.
- (c) It consists of, in whole or in part, any filthy, putrid or decomposed substance, or has been prepared, packaged or stored under unsanitary conditions where it may have been contaminated with filth or whereby, it may have been rendered injurious to health, or is packed in a container which is composed in whole or in part of any injurious or deleterious substance, which may render the content injurious to health, or bears or contains for the

purposes of colouring, any colour other than one, which is prescribed, or contains any harmful or toxic substance, which may render it injurious to health, or has been mixed with some other substance so as to reduce its quality or strength.

Substandard Drugs

Substandard drugs are universally described as genuine drug products that do not meet set quality specifications. The term substandard describes the quality of a drug produced by a genuine manufacturer, but which fails to meet the set specifications for its manufacture. Normally, manufacturers use specifications laid down in official Compendia such as the British Pharmacopoeia (BP), the United States Pharmacopoeia (USP) and the European Pharmacopoeia (Ph. Eur).

Unwholesome Food

Nigerian law describes an unwholesome processed food product as any food product, which consists, in whole or in part, of any filthy, putrid or decomposed substance, or has been prepared, packaged or stored under unsanitary conditions, where it may have been contaminated with filth, or whereby it may have been rendered injurious to health; or is packed in a container composed in whole or in part of any injurious or deleterious substance, which may render the content injurious to health. Others are food products that bear or contain for the purposes of colouring, any colour other than one which is prescribed; or contains any harmful or toxic substance which may render it injurious to health, or has been mixed with some other substance so as to reduce its quality or strength.

CHAPTER 5

GLOBAL TRENDS IN DRUG COUNTERFEITING

Counterfeiting of all products poses a great danger to every society. Almost all brands of commodities traded in international commerce are counterfeited. In most cases, it involves perfect copying of the original product. Some commonly known counterfeits are currencies, designer wristwatches, bags, perfumes, clothes, jewellery, pirated books and other stationery, audiocassettes, CDs, disks, diskettes, tyres, batteries and electrical products. These types of counterfeit usually cause economic losses, but there are others that have consequences that are more serious and require greater expertise to detect. Counterfeit medicine, motor spare parts and aircrafts fall into the category of products which not only constitute economic loss, but can also claim lives. Years back, thousands of defective Firestone brand of Bridgestone tyres were linked to several fatal car accidents in the USA, leading to a massive recall of the product in 2000 and 2001. On September 8, 1989, a Convair 580 airliner disintegrated over the North Sea, killing its 50 passengers and 5 crew members. Investigations revealed that this fatal crash was caused by counterfeit parts. It was specifically caused by substandard bolts and bushings, which led to the tail of the plane shearing off during flight.¹⁰

Counterfeiting is not a new phenomenon. However, it is now fast growing, and the effects are becoming rather alarming. Industry data show that 5–7 per cent of world trade, valued at about US\$280 billion, is lost to counterfeiting, and the problem is increasing yearly.¹¹ In the Information Technology industry, it is estimated that about US\$20 billion in products move through unauthorised channels annually. In the USA alone, losses to the spare parts industry due to counterfeits are estimated at about US\$3 billion. The losses in some parts of the Middle East are up to 30 per cent of the entire market size.¹² According to the International Federation of Phonographic Industries (IFPI), annual losses to piracy are estimated at about US\$4 billion, while the Business Software Alliance estimates their losses at about US\$11 billion annually.¹³

Counterfeiting of Pharmaceutical Products

The appearance of counterfeit medicines in international commerce was first mentioned as a problem at the WHO Conference of Experts on Rational Drug Use in Nairobi, Kenya, in 1985.¹⁴ Since then, public awareness of the problem has grown.

Counterfeiting of pharmaceutical products presents the worst form of man's inhumanity to man. It involves a transnational criminal network often controlled by a cabal of highly affluent and influential persons. It has far-reaching public health consequences. "In 2003, the World Health Organization (WHO) determined global sales of counterfeit drugs to be about US\$32 billion – 10 per cent of all medicines sold worldwide. It not only costs the pharmaceutical industry about US\$46 billion a year, but also endangers the lives of millions of people."¹⁵

Even though drug counterfeiting is a global problem, developing countries are more affected by this menace. The poor bear the brunt because they live under unhealthy conditions, feed poorly and are consequently more predisposed to ailments. Understandably, women and children are the most vulnerable. Lack of access to medicines has been identified as a problem in most developing countries, but access to counterfeit medicines is worse than lack of access. A considerable number of the poor nations of the world are found in Africa and they lack the capacity to deal with the problems of counterfeit medicines. This worsens the existing burden of poverty, diseases, lack of basic infrastructure, wars and other hardships.

Developed countries have, however, started to experience increasing reports of counterfeit drugs, fuelled by purchase of drugs via the Internet. "Internet sites that conceal their actual physical addresses sell counterfeits in over 50 per cent of cases."¹⁶ Recent findings show that the range is "from less than one per cent of sales in developed countries (but growing), to more than 10 per cent in developing countries, depending on the geographical area".¹⁷ Between 1984 and 1999, the WHO received 771 confidential and public reports of counterfeit drugs from different countries.¹⁸ Twenty-two per cent of these reports came from industrialized countries, while the rest came from developing countries. Between January 1999 and October 2000, 46 confidential reports of counterfeit drugs were received by WHO from 20 countries. About 60 per cent of these reports came from developing countries while the remaining 40 per cent were from developed countries.¹⁹ This goes a long way to confirm that counterfeiting of pharmaceuticals has become a global issue. The report further

shows that only a few countries were willing to provide information about cases detected. This silence is one of the major driving forces of counterfeiting.

Regional Overview

Asia

Counterfeit drugs, especially antimalarial drugs, have existed in Asia since the 17th century when Cinchona bark, from which Quinine is derived, was faked.²⁰ Reports indicate that many who mastermind drug counterfeiting are based in Asia, and are believed to be at the centre of a complex global network that is manufacturing and distributing fake medicines all over the world.²¹ It is reported that in some Asian countries, which have little regard for patent protection and intellectual property rights, companies may produce legitimate goods at one end of the factory and counterfeits at the other.

A WHO report of 1992 showed that, in Vietnam, there was a prevalence of counterfeit drugs nationwide, including the rural areas.²² Another WHO report indicated that India is responsible for about 35 per cent of the counterfeit medicine supply around the world. The report noted that this illicit business is worth about US\$200 million and represents 20 per cent of the world's total drugs market.

In 2001, 660kg of counterfeit medicines, 1,000kg of raw materials and boxes bearing the logo of another company were found in a counterfeiting factory in India.²³ In 1998, the State Drug Administration of China in a nationwide survey of the quality of medicines, found that 13.1 per cent of the 20,000 batches tested were either counterfeit or fell below minimal pharmaceutical standards while in 2002, it seized counterfeit drugs valued at US\$57 million and also closed 1,300 illegal factories.²⁴

In 2001, a five-country survey of Southeast Asia (Cambodia, Thailand, Myanmar, Vietnam and Laos) revealed that 38 per cent of 104 samples of Artesunate on sale in pharmacies and shops was counterfeit.²⁵ Some of the highest drug failure rates of these tests included the tuberculosis drug Rifampicin, and the antibiotic Co-trimoxazole, with 26 per cent and 24 per cent failure rates respectively. A total of 5,012,617 capsules of assorted counterfeit medicines including Amoxicillin and Ampicillin+Cloxacillin (Ampiclox) were seized in December 2003 in Myanmar.²⁶ Unregistered and notorious counterfeiting companies smuggled the seized counterfeits in from India and China. According to the WHO, counterfeit and substandard medicines that failed quality tests account for about 8.5 per cent in Thailand, eight per cent in Vietnam and 16 per cent in Myanmar.²⁷

Studies carried out on 1,359 samples in the Philippines showed that 8 per cent of products marketed were definitely counterfeit.²⁸

In Lebanon, in 1982, due to the civil war and Israeli invasion, many people needed drugs, but there was a dire shortage. Factories around Beirut were reported to be faking about 57 Western drugs. The Lebanese Government, despite being aware of this racket, refused to do anything to stop those companies or alert the public about the problem. These drugs were still killing people long after the guns had stopped.²⁹ In countries such as Lebanon and Thailand, it appeared that drug counterfeiting was officially allowed to thrive, as the governments failed to go public with knowledge of the counterfeiting problem. The official reason for the silence was that patients ran greater risks if the fear of fakes put them off taking the real product. Even in Britain, with its wealth of copyright and drug laws, this silence prevailed. A spokesman for the Association of the British Pharmaceutical Industry (ABPI), was reported to have stated that “it is difficult to declare a problem without damaging legitimate business”.³⁰

Europe

Approximately 240,000 packs of counterfeit medicine and 2 tons of raw materials worth US\$1 million were seized in Italy in the year 2000. The Medicines Control Agency (MCA) of the United Kingdom reported the detection of samples of counterfeit Viagra (Sildenafil citrate) and other unapproved Sildenafil products (content varied between 40 and 100 per cent of active ingredient).³¹ The Government Medicines’ Safety Agency seized £2.3 million worth of illegal and fake Viagra in 2003, and initiated numerous prosecutions.

In some countries of the former USSR, counterfeits account for up to 30 per cent of drugs in circulation, while in Ukraine this figure goes up to 40 per cent, and in the case of certain pharmaceuticals, it can be as high as 80 per cent.³² A report from Russia showed that 12 per cent of drugs in circulation are counterfeit.³³ In August/September 2004, counterfeit Cialis and Reductil were found in the UK and Netherlands supply system.³⁴ In September 2004, Dutch Health Inspection issued a statement indicating that five criminal networks produced and distributed counterfeit medicines in the Netherlands.³⁵

In February 2004, Portuguese authorities stated that thousands of counterfeit boxes were seized as part of an investigation into several networks involving doctors, nurses and pharmacy owners.³⁶ The Pharmaceutical Security Institute (PSI) in 2006 reported that the

Russian Federation, with 93 cases, topped the chart of 10 nations by counterfeits seized or discovered (Table 1).

Table 1: Top Ten Countries Ranked by Counterfeits Seized/Discovered³⁷

Country		Seizures/Discoveries
1	Russian Federation	93
2	China	87
3	Korea	66
4	Peru	54
5	Colombia	50
6	USA	42
7	UK	39
8	Ukraine	28
9	Germany	25
10	Israel	25

North America

The USA, with one of the most regulated and policed pharmaceutical markets, is not immune to the counterfeiting phenomenon. Patients treated with fake/counterfeit drugs have litigated their cases at different times. Two of the most popular counterfeited drugs in the US are Lipitor (cholesterol lowering medication) and Serostim (taken by HIV patients for weight gain).³⁸ In 2002, there were reports of counterfeit *Serostim*, *Epogen* (for treating anaemia), Gamimune (an immune booster), Zyprexa (for treating schizophrenia) and Combivir (Lamivudine+Zidovudine – antiretroviral), which in reality contained Ziagen (Abacavir Sulfate – antiviral). In 2003, the USFDA reported 3 lots each of counterfeit Combivir and Lipitor preparations, and about 200,000 bottles of Lipitor were recalled. In the same year, there was counterfeit alert from Solvay Pharmaceuticals, Inc. in response to the discovery of counterfeit Anadrol Tablets. The counterfeited Anadrol contained Androstenedione instead

of Oxymethalone, a synthetic anabolic steroid used by body builders. The Pharmaceutical Security Institute (PSI), with headquarters in Washington, reported that the value of seized, counterfeit and diverted drugs in the US alone was almost US\$200 million in 2003, a sevenfold increase from the previous year. Early in 2008, dozens of people were reported to have died in the USA following the use of Heparin, a blood-clotting agent. Investigations revealed the contaminant to be Oversulfated Chondroitin sulfate, which was alleged to have come from China. The Chondroitin sulfate cost US\$9 per pound, compared to US\$900 per pound for the genuine Heparin.³⁹ Oversulfated Chondroitin sulfate is similar to Heparin, but lacks the anti-clotting action of the drug, and has other adverse side effects. The level of incidence of counterfeit medicine in the USA has continued to increase since 1997 as shown below.

South America

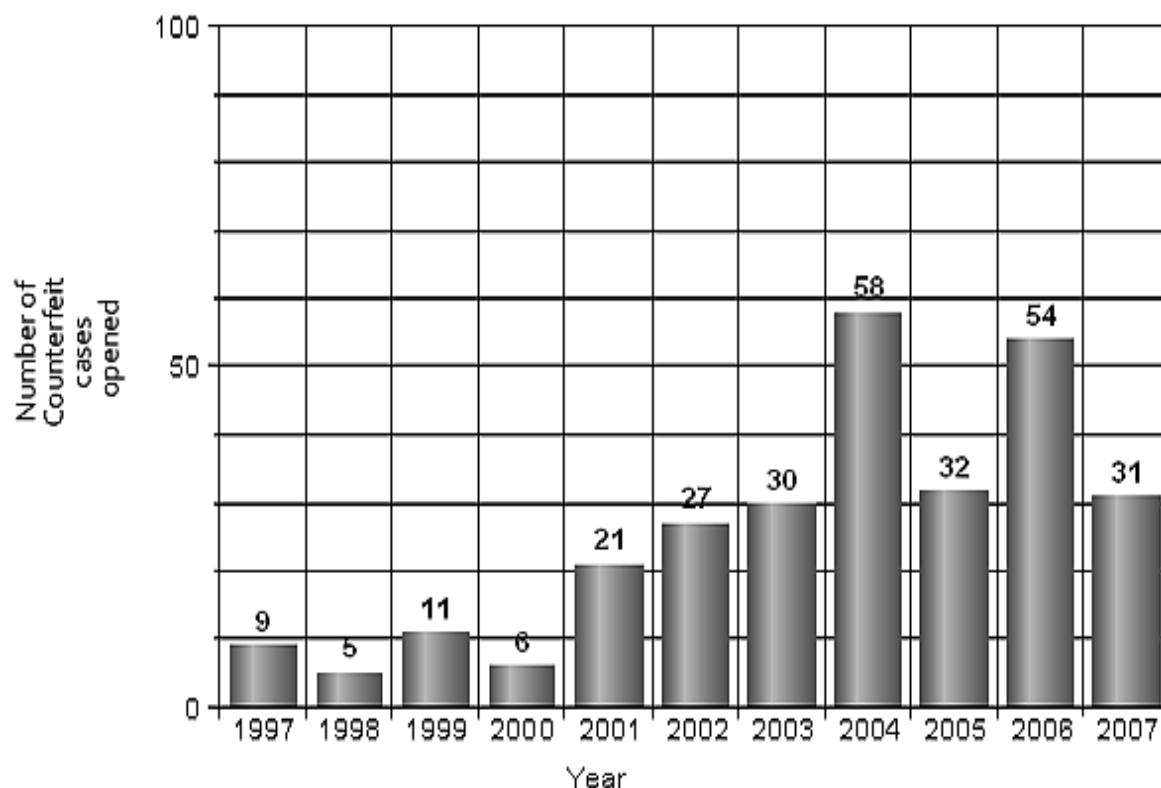


Figure 2: Counterfeit Drug Cases Opened by the USFDA per Fiscal Year (1997-2000)

Source: USFDA⁴⁰

In Argentina, counterfeit Voltaren, Tegretol, Hidergine and Reliveran (Novartis products) were detected in 1998. Investigations directed by Novartis resulted in the seizure of hundreds of US dollars' worth of counterfeit and adulterated medicines, as well as printing and packaging materials for Novartis and other pharmaceutical manufacturers. In 2000, six million ampoules of counterfeit Voltaren were seized in Colombia. In 2004, Colombian authorities declared that they have seized over one thousand tons of counterfeit medicines produced there.⁴¹

Africa

In Africa, the incidence of fake/counterfeit drugs is difficult to estimate for many reasons, some of which include: poor record-keeping, poor communication, non-existence or ineffectiveness of drug regulatory authorities, poor drug procurement practices, low literacy level, low awareness of the existence of counterfeit drugs, political instability and high level of smuggling.

The WHO Essential Drug Monitor (EDM) Report on transforming drug supply in Dar es Salaam, Tanzania, perhaps sums up the picture in most African countries as follows: "There was chronic shortage of drugs at health facilities, supplies were erratic, as was Government funding, poor drug supply management and irrational use of drugs. Drug quality was questionable and pharmacy premises were often unsuitable, hot, humid and cluttered with piles of drugs, some of them expired. Pharmacists had low professional visibility."⁴² This clearly mirrors the situation in other African countries. In a survey of 519 drugs in 3 African countries between 1991 and 1993, 77 drugs (18 per cent) were found to be substandard.⁴³ In 2000, counterfeit Ampicillin containing no active ingredient was found in Tanzania. In 2003, the Medicines Control Council of South Africa appealed to the general public and healthcare providers to refrain from purchasing or selling counterfeit Macrochantin 50mg (a urinary tract antiseptic) in their market. In the same year, there were reports of counterfeit antiretroviral Zidovudine 3D capsules (Zidovudine 200mg, Lamivudine 150mg, Indinavir 40mg) in Cote d'Ivoire. On analysis, the capsules were found to contain Zidovudine 201mg, Stavudine 40mg and another unidentified substance. In the Republic of Benin, inter-boundary trade amongst nations in the region constitute a "parallel market". The EDM also reported that Benin's National Office of Health Protection's estimate shows that about 85 per cent of Beninois patronise the parallel market. Those counterfeit drugs generally come from Gabon, Nigeria and some Asian, European and North American countries. Travelling salespeople who have no training and lack all requisite skills to dispense

drugs often control the parallel market. Within the West African sub-region, the inter-boundary trade in pharmaceuticals is very active. Nigeria has the largest drug market in the sub-region and many West African countries purchase their drugs from Nigeria.

Major Drug Tragedies

There have been many reports of deaths from the use of fake, counterfeit and poorly formulated drugs from all over the world. In 1937, in the USA, a Sulfanilamide elixir prepared with Diethylene glycol, a toxic chemical used as antifreeze, was responsible for the deaths of more than 100 people in 15 states. This incident prompted the enactment of the 1938 Federal Food, Drugs and Cosmetics Act. The new drug section, added to prevent such tragedies, gave the United States a new system of drug control, which provided superior protection. Twenty five years later, it saved the nation from an even greater drug tragedy – the Thalidomide disaster. In the mid-1960s, the use of Thalidomide by women to alleviate morning sickness in the early stages of pregnancy was on the increase. However, Dr Frances Kesley, the then head of the USFDA, refused to register Kevadon (Thalidomide), despite the enormous pressure mounted on her by a pharmaceutical company in Ohio. This was because scientific studies revealed some grey areas that she was uncomfortable with. Fourteen months later, when the Thalidomide babies horror shook the world, millions of mothers in the USA were spared the agony as a result of Dr Kesley's refusal to register the drug. However, this was not the case in other parts of the world where the use of the drug resulted in birth defects and deaths in over 10,000 babies in Europe, Asia and Africa. In Britain, the Thalidomide tragedy led to the establishment of the Committee on Safety of Medicines and the enactment of the Medicines Act of 1968.

In 2002, two HIV/AIDS patients in the USA experienced treatment failures after using counterfeit Serostim, a drug used to prevent weight loss in HIV/AIDS patients. They filed suits against the manufacturers and retailers for failing to adequately protect their product from counterfeiting. In 2001, an estimated 192,000 people died in China because of fake drugs.⁴⁴ Some died as a result of toxins in counterfeit medicines and others died from infections as a result of taking fake pills instead of antibiotics. From 1990 to 1992, in Bangladesh, another Diethylene glycol tragedy occurred when Paracetamol elixir, formulated with Diethylene glycol, caused fatal renal failure in about 236 children admitted to hospitals.⁴⁵ Consumption of Paracetamol cough syrup prepared with Diethylene glycol led to 89 deaths in Haiti in 1995, and 30 infant deaths in India in 1998.⁴⁶

In 1999, at least 30 people died in Cambodia after taking counterfeit antimalarials prepared with Sulphadoxine+Pyrimethamine, an older, less effective antimalarial, which was falsely sold as Artesunate.⁴⁷

During the meningitis epidemic in 1995 in Niger Republic, over 50,000 people were inoculated with fake vaccines, which resulted in 2,500 deaths.⁴⁸

In Nigeria, diseases or deaths from the use of counterfeit medicine abound, but due to poor reporting and recording systems, we do not have sufficient and reliable statistics to support this. In addition, deaths are sometimes attributed to superstitious forces. In the early 1980s, poorly compounded Chloroquine syrup was implicated in the death of several children who were being treated for malaria at the University of Nigeria Teaching Hospital (UNTH), Enugu. The actual number of deaths could not be ascertained, partly because many of the deaths were not even reported. In 1990, over 200 children died in Ibadan and Jos, Nigeria, after taking Paracetamol syrup produced with the toxic Diethylene glycol solvent. The tragedy occurred more than 50 years after the USA Diethylene glycol tragedy. Again, in 2008, Diethylene glycol contaminated syrup was implicated in the deaths of over 70 children in Nigeria.

In 2003, three children were reported to have died after open-heart surgeries in Nigeria due to fake Adrenaline (cardiac stimulant), low potency Suxamethonium (muscle relaxant), and contaminated infusions.

In 2004, three Nigerian hospitals reported cases of adverse reactions from the use of contaminated infusions. In the same year, 147 out of 149 brands of water for injection available in Nigeria were found to be non-sterile.

The incidence of substandard and counterfeit medicines continued to increase at alarming rates all over the world, requiring every country to develop an effective and sustainable regulatory framework to combat the ugly trend. NAFDAC is the agency charged with this responsibility in Nigeria.

CHAPTER 6

NAFDAC BEFORE APRIL 2001

The General State of NAFDAC

When I assumed office in April 2001, I was faced with the arduous task of reactivating a food and drug regulatory environment which had failed for over three decades, resulting in a crisis situation characterised by massive copying of original brands of drugs and other regulated products. Every part of the organisation was dysfunctional, from the staff to the laws and the facilities.

NAFDAC had qualified but poorly trained personnel, overwhelmed by the enormous task of regulating food and drugs in Nigeria. They did not seem to fully understand their responsibilities. Many of them overtly engaged in unethical practices, such as over-sampling of products for analysis, demanding gratification, unnecessarily delaying inspection and registration of products, and aiding and abetting official misconduct. Staff members were generally poorly motivated, had little direction and morale was very low. Staff postings were not based on merit, leading to ineptitude and inability to effectively perform their jobs. This generally lax state of affairs, coupled with massive corruption meant that revenues were not collected effectively and sanctions were not enforced, leading to a cash-strapped agency, unable to carry out its functions. The fact that imported products were registered without factory inspection also encouraged the dumping of fake and substandard products in Nigeria. Local manufacturing facilities were not strictly monitored and some of them manufactured their products under very poor Good Manufacturing Practice (GMP), which resulted in the production of poor quality or contaminated products. The existing laws were rather weak and did not act as a deterrent. Abuse of the judicial process, granting of inordinate injunctions to counterfeiters and long delays further exacerbated the problem. There was generally a very poor public awareness of the existence of counterfeit medicines and the functions of NAFDAC.

NAFDAC's head office accommodation was grossly inadequate. It was located in a rented, dilapidated two-storey building comprising six small flats, in a densely populated residential area of Garki, Abuja. The building was poorly equipped, without modern office facilities. NAFDAC also had 24 poorly furnished and ill-equipped state offices, and four under-equipped laboratories. This unpleasant working environment must also have contributed to making the staff unproductive and ineffective.

The State of Regulation

Criminals had dumped various forms of counterfeit medicines, unwholesome food, substandard cosmetics, chemicals and related products in Nigeria unchallenged for over thirty years. In addition to counterfeit pharmaceuticals, the following other substandard regulated products were in circulation:

- a) Expired products, products without expiry or "Best Before" dates, or products re-labelled with the intention of extending their shelf-life.
- b) Improperly processed and unregistered packaged water (popularly called pure water), resulting in frequent outbreaks of cholera and other water-borne diseases.
- c) Soft drinks, which were of lower quality than similar brands marketed in developed countries.
- d) Deceptively labelled fruit juices. Examples are: "100 per cent fruit juice", "no sugar added", "no added sweetener", "no preservative" – yet some of these juices which were made from fruits that are not naturally very sweet and had obviously been artificially sweetened.
- e) Beer and other alcoholic beverages, which did not bear their alcoholic contents and "Best Before" dates. Some were of poor quality, containing unacceptable levels of Nitrosamine, a natural by-product of brewing, which is carcinogenic.
- f) Improperly preserved yogurt prone to infection.
- g) Non-iodised salt, leading to poor brain development in children and goitre in adults.
- h) Bread with high Potassium bromate content. Over 95 per cent of Nigerian bakers continued to use Potassium bromate as a bread enhancer, despite the fact that it was banned in the early 1990s, for its implication in cancer, kidney failure, loss of hearing and breakdown of vitamins.

- i) Tins of baby milk filled with a mixture of cassava flour, sugar and powdered milk. Cassava flour has a high cyanide content, which may have led to the death of many babies.
- j) Processed foods that were expired, about to expire, or preserved with toxic chemicals.
- k) Processed foods and drinks containing unapproved sweeteners, colours, flavours and other additives, or those contaminated with bacteria, heavy metals, trace metals, radioactive materials and banned chemicals.
- l) Body creams containing bleaching agents such as mercury and hydroquinone, which can damage the skin and other organs, especially the kidneys.
- m) “Designer perfumes” produced with diluted concentrates filled into empty bottles of designer perfumes.
- n) Toothpastes without and, or with insufficient fluoride. Lack of fluoride in toothpaste causes tooth decay.
- o) Syringes with poor calibrations and blunt needles; non-sterile syringes, needles, surgical blades, blood bags, infusion sets, gloves and sutures.
- p) Condoms with poor tensile strength.
- q) Narcotics and controlled chemicals that can either serve as precursors for the production of illicit drugs or explosives and ozone-depleting chemicals, were imported and distributed without strict control.
- r) Products labelled “For Export Only”.

The counterfeiting of pharmaceutical products however, presented the greatest health risk, and therefore required urgent attention. Counterfeit medicines were first noticed in Nigeria in 1968, after Crown Agents ceased to be the sole distributors of pharmaceuticals. The problem worsened progressively until 2001, when Nigeria was rated as one of the countries with the highest incidence of counterfeit medicines. The average occurrence of counterfeit medicines in Nigeria was over 41 per cent according to the following studies done before 2001:

- Poole (1989) reported that 25 per cent of drug samples studied were fake, 25 per cent genuine and 50 per cent inconclusive.⁴⁹

- Ocheke et al. (1993) reported a failure rate of 41.4 per cent out of 379 drugs tested for percentage content of active ingredients with reference to the British Pharmacopoeia (BP) 1988 specifications.⁵⁰
- Taylor et al. (2001) reported that 48 per cent of drugs tested were substandard.⁵¹

NAFDAC's own study in 2002 showed that about 68 per cent of drugs in Nigeria were unregistered. Almost all drugs had been counterfeited. Counterfeiters target cost and volume. Antimalarials, antibiotics and vitamins are among the most used drugs in Nigeria. Of the three, antimalarials as a group had the least proportion of products with standard active ingredients.

Forms of Counterfeit/Fake Medicines Identified by NAFDAC

The following forms of counterfeit medicine have been identified in Nigeria:

- Drugs with no active ingredient(s): when a drug has no characteristic taste or smell, drug counterfeiters produce such a drug with only excipients (inactive carrier substances) like lactose, or even chalk, compressed into tablets, or filled into capsules. We also found capsules filled with olive oil and labelled as multivitamins.
- Drugs with insufficient active ingredient(s): when a drug has a characteristic smell or taste, drug counterfeiters add a fraction of the active ingredient(s) to deceive consumers. For instance, Chloroquine, which is an anti-malarial, is intensely bitter. Consequently, the drug counterfeiters add a little quantity of the active ingredient. The highest quantity of Chloroquine base that we found in the fake Chloroquine was 41mg as against the required 200mg. Another example is Ampicillin and/or Cloxacillin, an antibiotic that has a characteristic smell. The highest quantity of active ingredient we detected in the fake types was 50mg, as against the required 250 or 500mg.
- Drugs with active ingredient(s) different from those stated on the label: This is the worst type of counterfeit. When a drug is scarce or very expensive, counterfeiters use the name of such a drug to label any drug irrespective of the content. The following are some examples: Glibenclamide (an anti-diabetic) packaged and labelled as Norvasc (an anti-hypertensive); Paracetamol (an analgesic) packaged and labelled as Fansidar (an anti-malarial); Indocid (an anti-arthritis) packaged and labelled as Librium (a sedative).
- Clones of fast-moving drugs: these are fakes with the same quantity of active ingredient(s) as the original brands, and packaged to look exactly like the original brands. What the

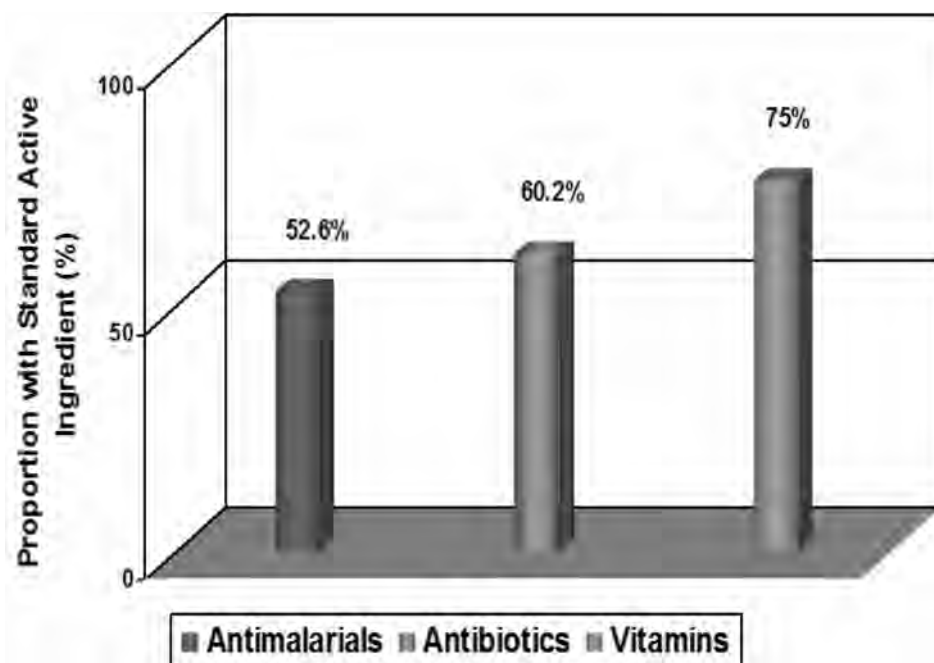


Figure 3: Proportion of Drugs with Standard Active Ingredients

Source: Adapted from F.B. Adenike: Pharmacy in Nigeria, 1998

fraudsters do not understand is that the minimal effective blood concentration of a drug, which determines the efficacy, is not only dependent on the quantity of active ingredient, but also on the quality, particle size, excipients, formulation techniques and other parameters. Fast-moving cosmetics, processed foods and drinks were also massively cloned.

- Expired drugs, drugs without expiry date, or drugs re-labelled to extend the shelf life; such drugs are also grouped as fake. An expiry or “Best Before” date is scientifically determined and attached to a product. After that date, it is no longer safe to use, and the manufacturer would no longer be liable for any ill-effect resulting from the use of the product. Due to the weak regulatory environment, large consignments of expired or about-to-expire drugs and other regulated products were regularly shipped into Nigeria unchecked.
- Herbal preparations fraudulently mixed with orthodox medicine: it was common practice for herbal medicine practitioners to mix their herbal preparations with potent Western medicine, to deceive consumers. For example, a herbal wound healer was found to contain Co-trimoxazole (an antibiotic). This phenomenon is not peculiar to Nigeria. In February

2001, Mosby's Drug Consult reported the case of a herbal rest and relax product distributed in the USA which had been found to contain Chlordiazepoxide (Librium – a sedative).

- Drugs without the full name and address of the manufacturer: in order to conceal their identity, counterfeiters sometimes give untraceable or non-existent addresses, such as a P.O Box no., on the packaging.
- Drugs not registered by NAFDAC: according to Nigerian law, any drug not registered by NAFDAC is not authorised to be produced, imported, distributed, sold or used in Nigeria. In other words, registration with NAFDAC confers marketing authorisation on all drugs and other regulated products. Most unregistered drugs are smuggled into the country.

Implications of Counterfeit Medicine

Fake drug is bad news. The fake drug trade is the worst aspect of corruption, because it affects life directly. Money can be regenerated, but life cannot be recreated. The counterfeiting of medicines is one of the greatest atrocities of our time. It is a form of terrorism against public health, as well as an act of economic sabotage. It is mass murder. Counterfeit drugs violate the right to life of innocent victims. I believe that the evil of counterfeit medicines is worse than the combined scourge of malaria, HIV/AIDS, armed robbery and illicit drugs. This is because malaria can be prevented or treated, HIV/AIDS can be avoided, armed robbers may or may not kill, illicit drugs are taken out of choice and by those that can afford them, but counterfeit medicine are taken by all, and anybody can be a victim.

Counterfeit medicines embarrassed our healthcare providers and eroded the confidence of the public in our healthcare system. They are implicated in kidney failure, liver damage, heart failure, and other organ dysfunctions. Counterfeit medicines mean that treatments fail, they lead to the development of drug resistance (especially in the areas of malaria and infectious diseases) and death. In some cases, patients no longer respond positively when treated with genuine antibiotics due to the emergence of resistant strains of microorganisms induced by previous use of fake antibiotics. Before the 1970s, malaria was treated like the common cold in Nigeria because of the efficacy of Chloroquine and Quinine. By the early 1990s, due to the development of resistant strains of the malaria parasites, partly induced by substandard antimalarials, second line drugs like Fansidar and Halfan were introduced to treat malaria. By the late 1990s, resistant strains against the second line drugs emerged,

forcing a switch to Artemisinin derivatives for treatment. Presently, we are on Artemisinin Combination Therapy (ACT). The question that keeps troubling my mind is – if drug counterfeiters succeed in faking ACT, where do we go from there?

As people were dying from the effects of counterfeit medicines, legitimate businesses were collapsing. Due to unfair competition, local drug manufacturers were going out of business, and many multinational companies divested out of frustration. Some of the companies included Boehringer, ICI, Sandoz, Merck, Aventis Pharma, Boots and Pfizer. Made-in-Nigeria drugs were banned by many West African countries. Other fake regulated products such as medical devices, processed food, cosmetics, chemicals/detergents and table water also have adverse health and socio-economic implications.

CHAPTER 7

DECLARING THE WAR

I received my letter of appointment as Director General of NAFDAC on April 11, 2001, and assumed office the following day. I asked Dr Dere Awosika, the then CEO of the National Programme on Immunisation (NPI), to accompany me to NAFDAC office in Abuja, to give me the much needed support. Before we left her office, I hurriedly drafted my first address to the management staff of the agency. My heart skipped a beat when I first saw the dilapidated three-storey building, in a residential area, with the NAFDAC signage on it. This was supposed to be the Corporate Headquarters of the Food and Drug Regulatory Agency of Nigeria! My shock was heightened when I walked into the building. The interior was more decrepit than the exterior. The scanty office furniture with hardly any modern office equipment was depressing. The look on the faces of the staff was not encouraging either. At the time when the former Director General was relieved of his appointment, the Directors of NAFDAC were also disengaged from service. An interim management team was then mandated to run the affairs of the Agency. No member of this interim management team was present to receive me. There were no handover notes from my predecessors, and our efforts to meet with any of them were unsuccessful. Frustrated, I went to the then Minister of State for Health, Dr Amina Ndalolo, and informed her that there was no handover note, and that there was nobody to hand the Agency over to me. She advised me to start with whatever I could lay my hands on. She went further to say that going back and forth to look for people who were not ready to cooperate with me would only waste my time and could become a distraction.

I thus started work immediately, holding my inaugural meeting with the staff in Abuja. I travelled to Lagos the same day to hold an all-day interactive meeting the following day, with the staff in Lagos, the Operational Headquarters of the Agency. Thereafter, I undertook a familiarisation tour of all the facilities in Lagos, including offices and laboratories. The situation in Lagos was even worse than that in Abuja. The laboratories were derelict, filled with obsolete non-functional equipment, and the general environment was quite depressing.

I became quite nervous. The level of decay was unbelievable, and the scope of the work that needed to be done was overwhelming.

Though lacking in experience, success on this job was crucial to me. The President of the Federal Republic of Nigeria had placed great trust and confidence in me by appointing me to the position, despite stiff political opposition. Furthermore, many Nigerians had lost their lives from the effects of counterfeit drugs. I personally had a bitter and traumatic experience of this when in 1988, I lost my favourite sister, Vivian Edemobi in her prime, at the age of 23. She had used fake insulin injections to manage her diabetes without success. She also developed an abscess from the use of the insulin, and the abscess never responded to the antibiotics she used, possibly because the antibiotics were also fake. That irreplaceable loss continued to be the driving force in my work. I also felt this was an opportunity to give something back to the country that made me who I am. Finally, I was determined to succeed, to prove the critics of my appointment wrong.

The ineffectiveness of NAFDAC as a Food and Drug regulatory organisation left the door open for massive importation of counterfeit drugs, tainted food and other substandard products. Counterfeit medicines were widespread throughout the country. The situation was so bad that no hospital, clinic or pharmacy could be 100 per cent sure that the drugs they dispensed to their patients were genuine. Powerful and affluent fake drug barons carried out their nefarious activities with impunity, using their clout and money to muscle NAFDAC staff and compromise other government agencies. Against this background, I declared an all-out war on counterfeiting.

Mr Tubosun Odusanya, the Personal Assistant to the former Director General, stayed on, working around the clock with me, to acquaint me with the system. I inherited a backlog of files that had been left untreated, some dating back eight months. Regrettably, some of those files contained offers for foreign-sponsored training for NAFDAC staff, which could have been of great benefit, and at no cost to the Agency.

2001 was the most hectic period of my life. Mr Odusanya and I worked all day, to the early hours of the next day, seven days a week, dealing with accumulated files. I eventually recruited my first Special Assistant, Mr Kalu Ugwumba, and my second Special Assistant, Mrs Lizzy Awagu, in May 2001. We all continued to work day and night. Subsequently, Mr Dioka Ejionueme joined us, initially as a consultant, and was later fully employed, along with other Directors and Deputy Directors. They also joined the rest of us in working long hours. We only gave ourselves breaks on Sundays, when we came to work after church. I did not

realise how hard I was driving everybody, until I had an unforgettable encounter with the husband of Mrs Yetunde Oni's secretary. Mrs Oni was the Deputy Director of Administration. Her secretary's husband, a senior official of the Central Bank of Nigeria, came to the agency and requested that I sign a letter to transfer his wife back to the Federal Ministry of Health. "This is not how to do government work," he retorted angrily. "My wife goes out in the morning, comes back at night, and cannot even bring the children back from school. She actually collapsed on one occasion." Apparently, this lady was very competent, and Mrs Oni pleaded with me to appeal to the lady's husband to change his mind about the transfer. When the appeal failed, I had no choice than to sign the letter.

We continued at this frantic pace, and by November 2001, I had a nervous breakdown. Upon my recovery, we had to stop working through the weekends.

I had no clear-cut ideas or strategies on how to fight the war, but I was continuously thinking about the work, jotting down ideas as they flashed through my mind. I always carried my pen and writing pad with me everywhere, in the car, at the office, at dinner, and even in church. At night, I kept the pad on my bedside table, and got up to write whenever any idea crossed my mind. Before my first encounter with Nigeria's press corps, I was advised by my family and friends to give evasive answers to their questions, to avoid making any mistake, given my supposed 'inexperience.' I was even tutored to say to the journalists: "I am still studying the place. I need time to fully appreciate the state of affairs at the Agency before deciding on the way forward. I will communicate my decisions to you in due course." Some journalists came to my office in Lagos to ask me about my plans for NAFDAC. I quickly repeated my memorised response. Dissatisfied, they probed further. I maintained my position. Then I heard someone say: "What are you going to do about pure water being produced everywhere, and most of it not registered by NAFDAC?" This was a left hook, demanding a specific response. My rehearsed answer became inappropriate. I heard myself saying: "Most of the pure water producers do not even understand the implications of what they are doing. We will start by organising workshops and enlightenment campaigns to educate them on the dangers of improperly processed packaged water. We will then teach them how to produce the right quality water, and encourage them to come and register their products with NAFDAC." They all appeared to be satisfied with this answer and the next day, it made headline news in most of the national newspapers. A week later, two of the journalists came back, asking, "What about the workshop for pure water producers?" Week after week, the press bombarded me with enquires about the promised pure water workshop, until we

hurriedly put a programme together. This was the genesis of our nationwide public enlightenment campaigns, which began in Lagos on June 21, 2001, and was later extended to all the states of the Federation, and the Federal Capital Territory, Abuja. Our success with the packaged water workshops informed the need for us to do the same with other stakeholders. All our workshops were interactive in nature. Each group was given the opportunity to ask questions, contribute ideas, and indicate ways in which they could support NAFDAC. While sensitising and educating the stakeholders, the public was also being sensitised and educated.

CHAPTER 8

STRATEGY I: RESTRUCTURING AND REORGANISING NAFDAC

Having been pressured into starting the public enlightenment campaigns, we quickly developed other strategies to support the fight. One strategy led to another. Staff reorientation and motivation were key, and the directorates needed to be restructured. We also needed to develop Standard Operating Procedures (SOPs) and Operational Guidelines. The existing offices and the old laboratories needed to be upgraded, while new ones needed to be built.

Staff reorientation, reorganisation and motivation exercises were simultaneously carried out, along with the restructuring of the Agency and the modernisation of our regulatory processes, through a holistic strategy of overhauling the entire system. Our target was to create an enabling environment for the refocused NAFDAC staff. While working relentlessly to refocus the staff for greater effectiveness, we also embarked on restructuring the entire organisation for operational effectiveness and efficiency.

Staff Reorientation, Reorganisation and Motivation

One of the first things I did on assumption of duty was to make a note of the things that needed to be changed in order to achieve a complete turnaround of NAFDAC. These included people, processes and systems. To me, “people” was the most important of these elements. Lee Iacocca also captured this in his autobiography, where he stated that, “in the end, all business operations can be reduced to three words, people, products and profits, and people come first. Unless you have a good team, you can’t do much with the other two.”⁵² After consultations with the staff, we agreed on the following: first, we had to conduct NAFDAC activities in a professional and businesslike manner, and in this regard, see ourselves as being in the business of safeguarding public health. Secondly, ours is a special call, and indeed a life-saving mission. Thirdly, fraudulent practice such as over-sampling of products for analysis, unnecessary delays in inspection and registration and aiding and abetting corruption in any form must stop. Fourthly, we could not afford to continue the way things were, and that all hands must be on deck to stop counterfeit drugs, tainted food products and other regulatory lapses.

The need for staff reorientation was inevitable and a change of mindset was critical to achieving the turnaround in the system. We needed a total change of attitude and in fact, a cultural revolution throughout the organisation. We therefore embarked on staff rationalisation and reorganisation. We took the following steps to reposition members of staff for better effectiveness:

- i. Staff found to be corrupt, redundant and incorrigible were retrenched. This was because a culture of blatant corruption pervaded the entire Agency. We identified the members of staff who were not ready to imbibe the new culture of change, and noted them for dismissal. Some of these recalcitrant staff challenged me openly, making statements, like: “We started this Agency. This is not how we do things here.” They felt uncomfortable with the entire change process, and could not hide their feelings. Some staff members evidently lived beyond their means, while others were reported by their colleagues to be corrupt. Still others were found to be lazy, redundant and irredeemable. Each report was fully investigated before decisions were taken. These groups, which made up about five per cent of the entire staff, were summarily dismissed, and we continued to dismiss corrupt and incorrigible employees whenever necessary.
- ii. We embarked on extensive staff training and re-training, both locally and internationally. This was necessary to equip them with the relevant skills required for effective regulation and control of food and drugs. Induction training was organised for newly recruited staff members, to acquaint them with all NAFDAC operations. We also organised specialised in-house training and computer appreciation courses for all staff members, and offshore training for a good number of them. Each month, we had at least 15 members of staff on training with different international organisations at no cost to the Agency. We regularly organised in-house training for all staff members on Good Manufacturing Practices (GMP), Hazard Analysis and Critical Control Points (HACCP), and other relevant areas. In July 2001, I issued a directive that computer literacy must be taken into consideration for all promotions, resulting in many of the staff taking computer training courses, both within and outside the Agency. As a result, NAFDAC employees were able to word-process their own documents. This has greatly improved our reporting systems and data management.

- iii. Staff redeployment was based on competence and area of specialisation. We invited a team of consultants who assisted us in deploying staff according to qualifications, competencies and suitability for defined job functions.
- iv. We recruited new staff, based entirely on merit, through very meticulous and effective screening exercises, conducted by external consultants and experts. During our first major recruitment exercise, advertisements were placed in most Nigerian newspapers, inviting interested and suitable candidates to apply. We received over 3,000 applications. Consultants were engaged to shortlist the candidates for the next stage. We invited the West African Examination Council (WAEC) to conduct aptitude tests for the 1,500 short-listed candidates. The successful candidates were interviewed before being employed. This was unprecedented for a government agency where tribalism, nepotism and political leanings are the order of the day.

In March 2008, we carried out another recruitment exercise to fill identified vacancies for first-line officers. A total of 15 job categories were advertised in three national dailies and prospective candidates were allowed six weeks to indicate their interest. Over 35,000 applications were received, sorted and short-listed by a reputable firm of consultants, selected from several others through due process. The 10,484 short-listed candidates sat for the aptitude test in Lagos and Abuja simultaneously on October 8, 2008. The aptitude test was conducted by Kewalarm–Chanrai Group, a foreign company that volunteered to assist us, at no cost to the Agency. They saw the move as a corporate social responsibility to Nigeria, and a modest contribution to the success story of NAFDAC.

- v. Our employment criteria were modified to include handicapped persons, making NAFDAC a truly equal-opportunity employer. However, we did not lower our established high moral and ethical standards, not even for this category of employees. I will illustrate this with two of such employees. Rukayat Olayinka Tebun (nee Babajide), a brilliant and determined young woman, came in a wheelchair to be interviewed for employment in the Agency. We hired her, in keeping with my determination to provide equal opportunities for all Nigerians. Though physically challenged, Rukayat rose above her disability in her carriage, conscientiousness to duty and amiable disposition. She presently works in the Administration Directorate where she continues to be a good ambassador for disabled persons in Nigeria. While in NAFDAC, she got married to Architect Dimeji Tebun. They are blessed with one

child. Another physically challenged employee started out well at the Central Laboratory Oshodi, Lagos. He was however, implicated in a case of fraud and was dismissed following the outcome of our investigations.

- vi. Nepotism, partiality and favouritism were totally discouraged in the new NAFDAC. For instance, my husband's younger brother, a staff in the Enforcement Directorate and a team leader, who usually led his team to investigate allegations of fake products was on one occasion, alleged to have demanded and collected a bribe of ₦600,000 (US\$5,220) from an importer of unregistered food products. He was said to have gone back for more and when the expatriate manager of the company refused to yield, he was alleged to have beaten him up. The owner of the company reported the case to me. Our investigation confirmed his culpability, and he was summarily dismissed. His dismissal created a lot of problems for me amongst my in-laws, but it effectively put everybody on notice that there would be no sacred cows in the war against counterfeit medicines in Nigeria.
- vii. We encouraged effective delegation of duties and staff empowerment at all levels. The new corporate culture of staff empowerment engendered their effective buy-in to the vision. The employees became committed to the change process when they realised that they were recognised as important partners in the restructuring effort. Directors were empowered to take decisions even in my absence. The standing instruction was that, in the absence of the Director General (DG), any Director acting for the DG, in consultation with the Director of a Directorate that had any issue, and the DG's Special Assistant, could take a decision on that issue. Furthermore, if any junior staff reported a case to a Director or a Senior Officer and action was not taken within one week, the junior staff was encouraged to report the matter directly to the Director General. This partly contributed to the dismissal of one of the Directors, and has greatly empowered the junior staff, while putting the senior officers on check.
- viii. There was constant staff performance evaluation, to ensure commitment and effectiveness. To check staff tardiness and absenteeism, we introduced clocking registers in every unit. The measure drastically reduced the frequency of excuses of "going to the bank", a common practice by public service employees in Nigeria. Any staff member found to be violating timekeeping policies was issued a query and disciplined appropriately. Two members of staff were dismissed for habitual tardiness.

Delaying the treatment of any document for more than 48 hours attracted a query, which could lead to suspension if unjustified. Memos were issued to that effect. To enforce this directive, my Special Assistant performed routine checks on mail and file movements.

- ix. Various welfare packages were introduced and sustained. We paid all over-due staff benefits, allowances and remunerations that had accrued over time. This included paying “thirteenth month” salaries to our employees as year-end bonuses from our internally generated revenues. This incentive drove them to work aggressively towards generating revenue, knowing that it was spent judiciously in running the affairs of the Agency, and for their collective welfare. To boost staff morale, we provided transport allowances and welfare packages for events such as marriages, births, burials, in addition to medical and several other benefits, knowing that an unhappy person cannot give his or her best at work. Computers, mobile telephones and walkie-talkies were made available whenever needed. We also established a crèche to cater for babies of our staff. This made the environment conducive for our nursing mothers to nurse their babies and be close to them during working hours, while still contributing to moving NAFDAC forward. The Council and Management of NAFDAC continually sought avenues to motivate staff towards greater productivity. In addition, our outstanding reputation, coupled with our good public image, constituted the highest motivating factor for our employees.
- x. Hard work, dedication and transparency were handsomely rewarded. Reward was in the form of recognition, promotion and exposure to relevant training. Letters of commendation, personally signed by me, were always written to deserving staff for any outstanding achievement. Whistle blowers who exposed importers or producers of fake/counterfeit products were rewarded appropriately. This explained why some NAFDAC staff members were prepared to spend their nights hiding in-between containers at the ports, even without overtime payments, to apprehend criminals. For example, the Deputy Director who brought the Nestle case to my knowledge was promoted to the rank of a full Director, while the junior officer who reported the case to her was promoted to the next level. Staff members who reported any fellow employee found to have compromised with defaulting companies were similarly rewarded. I believe very strongly that when hard work and integrity are not rewarded, corruption is promoted. A good example of this positive transformation came in

August 2007, when three members of staff went to Jordan for GMP inspection of some factories. Shortly after their return, while in Lagos, a representative of one of Nigeria's top pharmaceutical manufacturers came to me to find out what I did to my staff to bring about such a high level of transparency and honesty. Apparently, their partners in Jordan had offered the inspectors free hotel accommodation. They declined the offer, and rather requested to be shown a decent hotel that they could afford. They also refused to accept money offered to them by the company at the end of the inspection. The executives of the Jordanian company were pleasantly surprised because their experience with inspectors from other countries was different. They were all rewarded for their honesty.

- xi. Corruption was severely sanctioned and any form of laxity was penalised. Any staff caught negotiating or accepting a bribe from a manufacturer or importer in the course of his or her duty was dismissed. Staff members who aided or abetted such actions received the same treatment. This was necessary to reverse the entrenched culture of bribery and corruption. On one occasion in 2001, one of our accountants was given a mobile telephone by one of our contractors, just about the time GSM was newly introduced in Nigeria. She became hysterical, screaming within the hearing of other members of staff: "I didn't ask him for any phone! Oh! I didn't ask him for anything! Oh...!" She knew the damage that soliciting for gifts from a contractor could do to her career. Our most recent initiative in the fight against corruption was the formal inauguration of a seven-member Anti-Corruption and Transparency Unit (ACTU), in 2008. I charged the members to lead by example, and urged them to come up with programmes that would sensitise our workforce on what constitutes an offence under the Independent Corrupt Practices and Other Related Offences Commission (ICPC) Act 2000.
- xii. Heroic acts were adequately compensated. A new employee, only three months into the job, and acting on information, followed a vehicle he suspected was carrying counterfeit medicines across the Nigerian border with the Benin Republic. He followed the vehicle with his rickety car until it stopped to refuel. Hiding his car in a nearby bush, he crept up to the refuelling vehicle, punctured the tyre and dashed back into the bush. He succeeded in getting police assistance from the nearest checkpoint to apprehend the group, which turned out to be fake drug smugglers, confirming his initial information. He received a commendation for his courage and commitment to

duty. He was also recommended for foreign training. The head of his unit questioned the decision to send an unconfirmed new staff member on an overseas trip. I simply retorted that his heroic activity had confirmed him.

- xiii. Leadership by example is highly emphasised at all levels. I always practised exactly what I expected of my staff members, to earn their respect and to guarantee their full commitment to the change process.

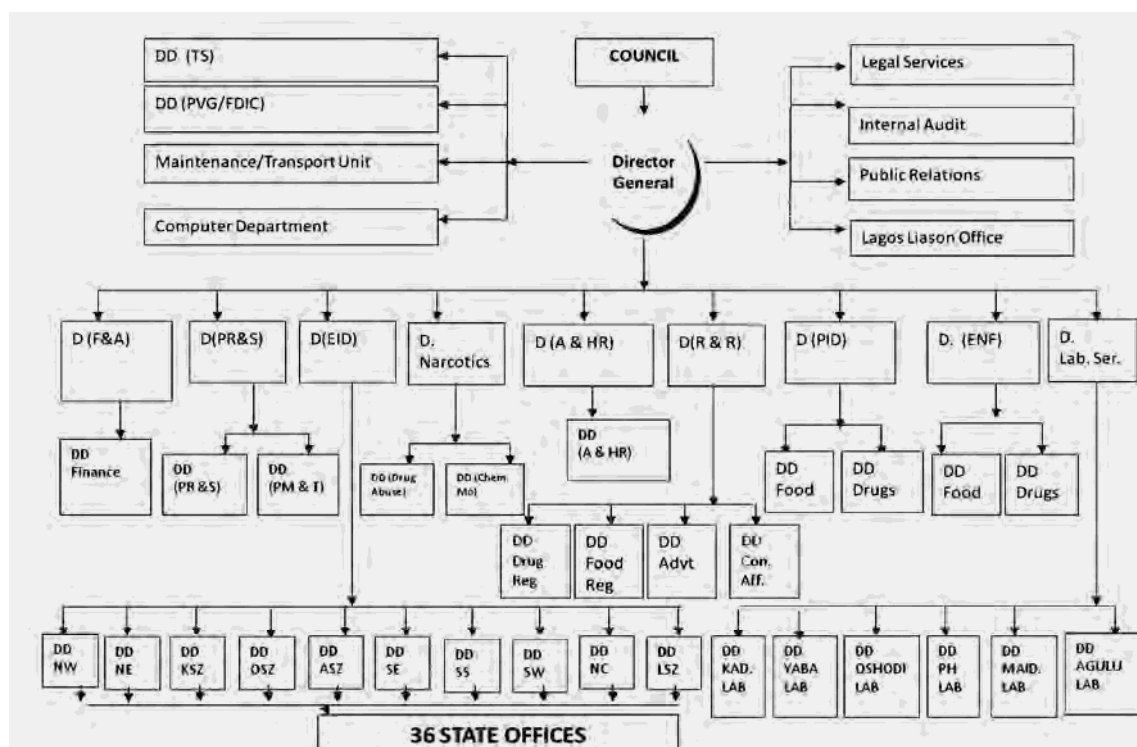
These initiatives, geared towards motivating the team to work as if they were in a private corporation, were a departure from what is usual in government organisations, which were characterised by nepotism, mediocrity and lack of commitment.

Within six months in office, we were fortunate to have on board a Chairman and Council members who shared the new vision for NAFDAC. Encouraged by the Council Members, we organised retreats for them and for our management in relaxed and serene environments. We formulated strategies and shared our new vision, mission and goal.

Restructuring the Organisation

The organisational structure I inherited was problematic. NAFDAC had only six Directorates. The Inspectorate Directorate handled the Establishment Inspection and Ports Inspection, which made it ineffective. There was no Enforcement Directorate and this hampered the implementation of sanctions. We therefore initially expanded the Agency into eight functional Directorates. The creation of two new Directorates, namely the Ports Inspection and Enforcement Directorates, further positioned the Agency to effectively tackle the problems emanating from inspection lapses and poor enforcement activities respectively. We considered these as keys to stopping the importation of counterfeit medicines, mopping up counterfeit medicines already in circulation, and enforcing standards and sanctions. With this expansion, NAFDAC's organisational structure was changed to a more functional one.

In 2008, the Office of the Head of Civil Service of the Federation stipulated that there should be a reorganisation of the Administration and Finance Directorate in all Nigerian Federal Government Ministries, Departments and Agencies (MDAs). Following the directive, in August 2008, we reorganised our former Administration and Finance Directorate into the Administration Directorate and the Finance and Accounts



Key: D – Director; DD – Deputy Director; F&A – Finance and Accounts; EID – Establishment and Inspection Directorate; A&HR – Administration and Human Resources; PR&S – Planning, Research and Statistics; R&R – Registration and Regulatory Affairs; ENF – Enforcement; PID – Ports Inspection Directorate; Lab. Ser. – Laboratory Services; TS – Technical Services; PVG – Pharmacovigilance; FDIC – Food and Drug Information Center; Reg. – Registration; Advt. – Advertise; Con. Aff. – Consumer Affairs; Chem. Mo. – Chemical Monitoring; NW – North West; NE – North East; KSZ – Kadun Special Zone; OSZ – Onitsha Special Zone; ASZ – Aba Special Zone; SE – South East; SS – South South; SW – South West; NC – North Central; LSZ – Lagos Special Zone; KAD. LAB. – Kaduna Laboratory; PH. – Port Harcourt; MAID. – Maiduguri

Figure 4: Organisational Chart of NAFDAC

Directorate. The updated NAFDAC Organisational Flow Chart is shown in Figure 4, while the detailed functions of each of the nine Directorates are outlined in Appendix 4.

Physical Infrastructural Improvement

NAFDAC also embarked on a major improvement and regeneration of the existing physical structures, and acquisition and development of new ones.

Laboratory Network

Our laboratory network forms the core of our operations. In order to make pronouncements on the quality of regulated products, we needed to be sure of the integrity of the laboratory tests upon which those pronouncements were based. The laboratory complexes I inherited were grossly inadequate for a food and drug regulatory agency. We therefore needed to upgrade them to world-class standards, and we achieved considerable success in this regard. We refurbished and upgraded our four laboratory complexes located at Oshodi and Yaba in the Western Region, and Kaduna and Maiduguri in the Northern Region with state-of-the-art equipment, and established an uninterrupted supply of premium quality chemicals and reagents. Our Yaba, Lagos laboratory is now fully accredited by the WHO and the European Union (EU). The Oshodi, Lagos laboratory is presently undergoing accreditation. Our new Port Harcourt laboratory located in Rivers State, in the South-South geopolitical zone, was commissioned on March 31, 2006. Nigeria, being a developing country, suffers from intermittent power outages and inadequate supply of potable water. All our laboratory complexes were therefore equipped with power generating plants and boreholes for uninterrupted supplies of electricity and treated water.

We proposed the construction of a laboratory complex in the South-East zone due to the need to have easy access to functional laboratories to boost our regulatory efforts in all the geopolitical zones of the country, since we have adequately provided for the Northern, Western and South-South Regions. We also planned another laboratory complex in Calabar, in Cross River State, as Calabar has been designated as an Export Processing Zone (EPZ), and its seaport is a designated port of entry for drugs and pharmaceutical raw materials. We approached the governors of Enugu and Cross River States for land allocation and they obliged by allocating plots of land to the Agency. The Agency's Governing Council did not hesitate to approve immediate construction work on the two parcels of land. While the Calabar project took off in earnest, that of Enugu did not materialise because the parcel of land allocated to us was found to be encumbered and the aggrieved owners chased away our contractors and destroyed both the work they had already done and their construction equipment. The Enugu State Government then gave us another plot of land located within the residential area of Coal Camp Extension, which we found to be grossly inadequate in size and less than ideal in terms of location. By October 2002, when we could not secure another piece of land from the Enugu State Government, the Governing Council directed that Anambra State Government be approached for a parcel of land within Awka metropolis.

The Council reasoned that having our laboratory in Awka was a viable alternative because of its nearness to Onitsha, the commercial nerve centre of that zone. We contacted the State Government, which quickly allocated to us, a piece of land located opposite Nnamdi Azikiwe University in Awka and the contractor mobilised to site immediately. In Awka, the indigenes did not allow the contractor to start work. Unknown persons built a fence overnight on the same parcel of land. The contractor's materials, which were on site, were seized and destroyed. All attempts to get the State Government to intervene in this matter or for an alternative site to be allocated failed. Efforts to secure a reasonably sized piece of land from some communities along the Enugu–Onitsha Road did not yield any positive result either. In the midst of these failures, in January 2003, a parcel of land measuring about 100 hectares was found in Agulu community, along the Amawbia–Ekwulobia–Orlu Road, within the Awka Capital Territory. It is also important to note that the land has a common boundary with the Nnamdi Azikiwe University College of Pharmacy, and is close to the office of the West African Examinations Council (WAEC), all of which are Federal Government establishments. We did not have any difficulty in securing the consent of both the community and the Anambra State Government for the use of the land for the construction of our laboratory complex. The Agulu land, therefore, came as a child of necessity when all our efforts to secure suitable parcels of land in Enugu and Awka townships failed.

Regional and State Offices

Until 2001, NAFDAC had offices only in 24 states of the Federation. With the 12 new state offices we established, all 36 states and the Federal Capital Territory, Abuja, are now covered by the Agency. Six zonal offices have also been established to coordinate the activities of the state offices in each of the zones. Also, three Special Inspectorate Offices have been created in the cities of Onitsha, Aba and Kano. These three cities have the largest drug markets in Nigeria. In addition, three Narcotics Offices were established in Abeokuta, Lagos and Port Harcourt. We constructed land border offices in the border areas of the country and these provided the infrastructure needed to enforce the ban on importation of regulated products through land borders. Portakabins were provided at all seaports to serve as offices for the Agency's port inspectors.

Warehouses

In the past, NAFDAC was confronted with the disturbing situation whereby seized products were stored in the owners' warehouses during investigation. We therefore built two new warehouses in Oshodi Lagos; one for thermolabile (i.e. heat-sensitive) products, and the

other for thermostable products. Having our own warehouses put us in full control of all seized products while we investigated any issues relating to such products. At the end of investigations, the products were either released to their owners if proven to be fit for human use, or destroyed if otherwise.

Corporate Headquarters

The acquisition of our new Corporate Headquarters in Abuja was the crowning glory of all our efforts to rebuild the organisation. It was indeed a monumental achievement for a government agency that was 10 years old at the time of purchase. Even more impressive was the fact that all the funds we used to purchase the property were internally generated. This edifice not only enhanced the agency's corporate image, but also provided a conducive environment for staff operation.

Other Infrastructural Improvement

We provided power-generating sets for all our offices and laboratories nationwide, to ensure continuous supply of electricity. We purchased new vehicles and repaired dilapidated staff buses and utility vehicles. We also installed computers, telephones, photocopiers, fax machines and other office equipment in all our offices. The provision of functional Internet services was done within the first three months of my administration. Our website is now operational and regularly updated. Our web address is www.nafdac.gov.ng and our e-mail addresses are nafdac@nafdac.gov.ng and nafdac.lagos@alpha.linkserve.com. Our structure, guidelines, SOPs, speeches, and other relevant information were all posted on the website. We looked forward to the construction of our Operational Headquarters in Lagos to resume the planned implementation of a Wide-Area-Network (WAN), which was aborted due to the arson attack on our offices in Lagos in March 2004. When completed, the WAN will connect our Abuja Headquarters to other offices across the country, in order to facilitate free flow of communication.

Despite all the difficulties encountered in the task of rebuilding NAFDAC, we were fully convinced that with determination and hard work, we would succeed.

We have a new NAFDAC, an Agency alive to its statutory responsibilities. At the 2002 and 2003 annual Nigeria Economic Summits, NAFDAC was showcased as a moribund public institution which was resurrected back to life.

CHAPTER 9

STRATEGY II: OPERATIONAL STRATEGIES

The Agency identified poor monitoring and enforcement as the weakest links in the chain of our regulatory activities. To address these problems, the management evolved new operational strategies to eradicate counterfeit medicines and other substandard regulated products, and create a strong regulatory environment. The strategies include developing new regulations, reviewing tariffs, developing guidelines and standard operating procedures, targeting the sources of counterfeit medicines, increasing surveillance at ports of entry, mopping up counterfeit medicines and other substandard regulated products in circulation, and monitoring the GMP of manufacturers, among others.

New Regulations

Nigerian Food and Drug laws were non-deterrent, unwieldy, overlapping, and sometimes conflicting. We were however, expected to operate with these laws in spite of their deficiencies. Since regulations, which are sub-legislation, are easier to promulgate and our principal laws empower us to do so, we have in the interim created regulations within the laws to enable us operate effectively. Consequently, we initiated a review of the existing regulations with representatives of the relevant stakeholders, and this resulted in the repeal and re-enactment of some old regulations, as well as the enactment of new ones. Out of the 14 existing regulations, nine were repealed while five were retained. Twenty-six new regulations were promulgated and 30 have been drafted and are ready for approval. Others are at various stages of processing. A few of our regulations are listed hereunder, while the comprehensive list is contained in Appendix 5.

1. Herbal Medicines and Related Products (Registration) Regulations 2005. This outlined for the first time the procedures for applying for the registration of herbal medicines in Nigeria and made it an offence to deal in any unregistered herbal product.
2. Marketing of Infants' and Young Children's Food and other Designated Products Regulations 2005. This is the first time a Nigerian legislation would capture the

International Code on Marketing of Breast Milk Substitutes (BMS) and the subsequent resolutions of the World Health Assembly (WHA). The regulations are designed to protect, promote and sustain breastfeeding, and discourage unwholesome marketing strategies by manufacturers and distributors of BMS.

3. **Cosmetics (Prohibition of Bleaching Agents) Regulations 2005.** This repealed the Cosmetics Products (Prohibition of Bleaching Agents, etc.) Regulations 1995 and now allows the inclusion of Hydroquinone in cosmetic products. However, the Hydroquinone content must not exceed the internationally acceptable limit of two per cent.
4. **Donated Drug and Related Products Regulations.** This seeks to discourage the dumping of drug products in the country and takes into account the WHO guidelines on drug donations. Demands for donated drugs must be initiated from the health facility requiring the donation and not from donors who may be seeking to offload their obsolete or about-to-expire drugs.

Developing our regulations is a well-articulated, step-wise procedure that ensures transparency and takes into account inputs from stakeholders. This is aimed at promoting easy compliance with the regulations when concluded and finally coming into effect. The procedure involves the identification of the need for a regulation by the Regulatory Affairs (RA) Division of the Registration and Regulatory Affairs Directorate, or any other Directorate within the Agency or at a product approval committee meeting. The regulations unit of the RA Division sources information from credible international organisations such as the WHO and FAO websites, or websites of national bodies such as the United States Food and Drug Administration (USFDA), EU etc. The draft regulations are considered by an in-house Standards and Regulations Committee, which is domiciled in the RA Division. The corrections and inputs of the Committee are reflected in the draft regulations circulated to members and endorsed at the next Committee meeting. The draft regulations are later sent to the relevant groups and posted on our website for stakeholders' comments and input. All acceptable comments and input are considered before the draft regulations are sent to our Governing Council, which considers them and sends them to the Honourable Minister of Health and the Federal Ministry of Justice, through the Legal Unit in the Director General's Office. The regulations are finally sent to the Federal Government Printing Press and gazetted for use by the public after consideration and approval.

At the time of concluding this book, the following regulations have been drafted and have reached an advanced stage of consideration by our Standards and Regulations Committee. They are: Good Clinical Practice (GCP) Regulations; Good Distribution Practice (GDP) for Pharmaceutical Product Regulations; current Good Manufacturing Practice for medicinal products regulations; and good Pharmacovigilance regulations.

Strict Enforcement of Registration Guidelines

We have streamlined and strengthened our registration processes with some administrative guidelines, which include the following:

- All products must comply with documentation and inspection requirements, laboratory standards, and labelling requirements in accordance with regulations before they can be registered.
- The guidelines for the renewal of registration for drugs and other regulated products must be strictly followed.
- All NAFDAC registered products must bear a NAFDAC REGISTRATION NUMBER on their labels. This enables the public to identify registered products.
- Renewal of drug registration is done every five years.

Regulation and Control of Clinical Trials

Clinical trials have always been a requirement for NAFDAC registration of new pharmaceutical products in Nigeria. Unfortunately, in the past, NAFDAC did not have strict guidelines for clinical trials. To fulfill this regulatory oversight, we established a Clinical Trial Unit in the Registration and Regulatory affairs Directorate and developed the necessary regulations and guidelines for clinical trials for new drug products.

Targetting the Sources of Counterfeit Medicines

In the bid to prevent fake products leaving the countries of manufacture for importation into Nigeria, we developed some administrative guidelines, which took effect from January 2, 2002. They include;

Mandatory Overseas Factory Inspection

NAFDAC officials must inspect factories anywhere in the world that produce drugs, food and other regulated products for sale in Nigeria. This is to establish satisfactory Good

Manufacturing Practice (GMP) before registration of their products. From 2002 to 2008, 1,022 members of staff have carried out about 380 foreign GMP inspections.

Establishment of Independent Analysts in India, China and Egypt

In India, China and Egypt, we appointed independent analysts who certify all drugs before they are exported to Nigeria. The companies are Quality Consultancy Services (QCS) in India, the Tianshi Group of Companies Limited (November 2003 to November 2008) and NHU Laboratories (from November 2008) in China and Inspection and Testing Group, represented by Dr Omar Sayed in Egypt. From June 1, 2002 all drugs shipped from India to Nigeria had to be accompanied by a confirmed Clean Report of Inspection and Analysis (CRIA) issued by QCS. From November 15, 2003 to November 14, 2008 all drugs shipped from China to Nigeria had to be accompanied by a CRIA issued by the Tianshi Group of Companies Limited, and since November 15, 2008 they have required one from NHU Laboratories. From April 1, 2006, drugs leaving Egypt for shipment to Nigeria also had to be accompanied by a CRIA issued by the Inspection and Testing Group. NAFDAC does not pay for the services of the analysts. The cost is borne by the drug exporters.

Pre-shipment records from India show that legitimate businesses are complying with these new guidelines. Between January 2002 and October 2008, 14,371 products were analysed by QCS and 13,741 CRIAs were issued, while 74 products failed analysis during this period. Similarly in China between January 2004 and October 2008 data received from our Chinese analyst showed that 1,001 products were analysed and 991 CRIA were issued, while 10 products failed analysis during this period.

Mandatory Pre-Shipment Information

We made it mandatory for all drug importers to provide pre-shipment information to the Agency before the arrival of any shipment into Nigeria. The pre-shipment information includes the chemical name of the product, the brand name, the active ingredients and the strengths, the dosage forms, pack sizes, quantities, NAFDAC registration number, country of manufacture, name and address of manufacturer, country of shipment, name of vessel, expected date of arrival and port of entry.

Requirement of Certificate of Free Sale for Registration

A drug or any other regulated product presented for registration must be confirmed to have been freely used in the country of production. To this end, we require that the Certificate of Free Sale, signed by the Minister of Trade or Industry of that country and authenticated by

the Nigerian Embassy, or any Commonwealth Mission, if there is no Nigerian Embassy in that country, be submitted along with the rest of the required documentation. This Certificate of Free Sale must clearly state that the product is freely used in the country of production. Any regulated product not used in the country of production will not be accepted in Nigeria for registration; hence products labelled “For Export Only” are not allowed to be registered or used in Nigeria.

Requirement of NAFDAC Clearance for Bank Transaction

We reached an agreement with all Nigerian banks to only process financial documents for drug importation after clearance with NAFDAC. This agreement is now an official policy of the Federal Government of Nigeria and is implemented by the Central Bank of Nigeria.

Strengthening Surveillance at all Ports of Entry

The creation of the Ports Inspection Directorate for effective surveillance at all ports of entry and the Enforcement Directorate for the enforcement of regulations, led to increased seizures of counterfeit medicines and other substandard regulated products. Hitherto, land and sea borders were major routes of importation of regulated products. As a result of intensified surveillance at the borders, fake and substandard products’ dealers resorted to air freighting their cargo. Consequently, NAFDAC, with the support of the Ministry of Aviation, issued new guidelines, prohibiting all aircraft from carrying drugs into Nigeria without obtaining NAFDAC authorisation from their clients. We wrote to all the airlines informing them that any aircraft caught bringing counterfeit medicines into Nigeria would be grounded. Advertorials were also placed in print and electronic media to this effect. When it became very difficult for them to freight the drugs by air, dealers resorted to the use of speedboats and other forms of water transportation.

Mopping up Fake Products in Circulation

Cognisant of our many porous borders, we embarked on planned, continuous and sustained surveillance in all markets and retail outlets for drugs and other regulated products.

We carried out routine sampling, checking and testing of all NAFDAC registered products in circulation. We also traced dealers of fake regulated products through reports received from victims and health professionals and tip-offs from the public. Some of these reports assisted us in identifying the sources of large consignments of counterfeit medicines and other substandard regulated products.

In 2004, following reports from doctors regarding adverse reactions to some infusions used on their patients, a nationwide infusions sampling exercise was carried out and results confirmed that some batches of infusions produced by four indigenous companies were contaminated with microorganisms. This frightening discovery informed our decision to ensure that water for injection was screened, the outcome of which was even scarier. A staggering 147 of the 149 brands of water for injection, which we screened, were found to be non-sterile.

In 2003, Nigerian journalists reported the deaths of three children following open-heart surgeries. Our investigations confirmed that fake and substandard Adrenaline (cardiac stimulant), Suxamethonium (muscle relaxant) and contaminated infusions were used during the operations.

Regular raids were carried out on drug hawkers and their drugs confiscated and destroyed. Continuous surveillance led to the closing down of drug shops, supermarkets and eateries and the closure of three major drug markets: Aba for three months in 2002, Kano for three months in 2004 and Onitsha for almost three months in 2007. To achieve a high level of success with our mopping-up exercise, we issued the following guidelines:

- Any drug seller who fails to provide proper invoices of purchases, with full names and addresses of their suppliers, would have their drugs confiscated and destroyed. This was to enable us to trace the big-time importers, producers and distributors of counterfeit medicines.
- Any landlord whose premises were used for the storage of fake regulated products would be required to turn in his or her tenant and failure to do so would result in him or her being arrested and prosecuted for aiding and abetting a fake product dealer. This guideline was issued because of the frustrations we faced in evacuating many lorry loads of counterfeit medicines from warehouses on tip-offs without anybody accepting ownership. On one occasion in Lagos, it was only after the landlord of the warehouse was arrested that the owner of the counterfeit medicines appeared.

Monitoring the GMP of Local Manufacturers

To ensure that local manufacturers of food, drugs and other regulated products manufacture good quality and safe products, we inspect and certify the GMP of factories regularly. The different types of inspections are as follows:

- (a) **Advisory Inspection:** When a producer has acquired premises and machines, NAFDAC officials inspect the factory and offer advice on production flow, the staff qualifications needed and the standard operating procedures (SOPs) required for the factory to be GMP compliant. This simplifies the procedures for the local manufacturer who may not have adequate resources to employ the services of consultants. The advisory inspection is free and optional for the new manufacturers.
- (b) **Pre-Production Inspection:** This is a general GMP assessment inspection carried out in respect of pharmaceutical products, to assess the manufacturing facilities, personnel and location of new production plants. This does not apply to other regulated products.
- (c) **Pre-Registration Inspection:** This inspection is designed to further assess GMP and to evaluate the drug formulation intended for manufacture.
- (d) **Production Inspection:** This type of inspection is carried out for all regulated products. It is to ensure compliance with GMP before commencement of production.
- (e) **Routine Inspection:** This is a spontaneous inspection carried out at a factory without prior notice to the manufacturer, to monitor the normal activities of the plant and assess its compliance to GMP standards. The surprise element ensures that manufacturers are kept on their toes at all times.
- (f) **Investigation Inspection:** As the name implies, this type of inspection is usually investigative, prompted by consumer complaints, requests from the public, or alerts from the government, media, embassies or other interest groups.
- (g) **Surveillance Inspection:** This type of inspection is usually carried out in areas of interest to us. Surveillance activities enable us to detect malpractices such as adulteration and faking of products, production of unregistered regulated products and non-compliance with requirements which the manufacturer met at the time of product registration.
- (h) **Follow-up Inspection:** This inspection is carried out when compliance directives have been issued to manufacturers following unsatisfactory GMP inspections. It is conducted to ascertain that the directives issued have been fully effected. Failure to do so would result in the case being transferred to our Enforcement Directorate for appropriate sanctions.

Compliance directives are issued where lapses are observed. Administrative penalties are imposed when there is a failure in complying with given directives. Prosecution is as a last resort, if the manufacturer is found to be recalcitrant, or the level of violation has serious adverse implications on the lives and well-being of consumers.

Encouraging Self-Regulation by Regulated Product Manufacturers

We encouraged self-regulation among drug manufacturers by insisting that product registration or its renewal, or concessions such as administrative approval, would only be given to companies that belong to the Pharmaceutical Manufacturers' Group of the Manufacturers' Association of Nigeria (PMG-MAN). Drug importers are also not allowed to register or renew their drug registration if they do not belong to an accredited association of drug importers such as the Association of Pharmaceutical Importers of Nigeria (APIN), Indian Pharmaceutical Manufacturers and Importers in Nigeria (IPMIN) or other similar organisations. We extended this rule to food and beverage manufacturers. This strategy greatly improved regulation within the industry, which made our work easier.

Tariff Review

Although NAFDAC, being a Government Agency, is expected to be fully funded from the Nigerian Government Federation Account, the funds we received from that account were grossly inadequate. Determined to succeed in turning around NAFDAC in a sustainable way, I had to develop creative means of generating the funds needed to achieve this mission. We funded the rebuilding and restructuring of the Agency from internally generated revenue. The funds came from a combination of registration tariffs and fees charged as administrative penalties for offences. In line with current global trends and in order to improve on our existing services and processes as well as promote the local pharmaceutical industry, the old tariffs that had been in use since 1994 were reviewed in December 2001, because they were out of tune with the present economic realities. Four-digit increases in operational costs, coupled with the need to acquire sophisticated modern analytical instruments – such as High Performance Liquid Chromatographs (HPLC), Gas Chromatographs and Atomic Absorption Spectrophotometers – and the maintenance of the old ones for better effectiveness, made the old tariff regime inadequate. It was also necessary to ensure an adequate supply of top quality analytical reagents and chemicals. There was the need to increase our testing parameters for products in order to ensure conformity with international standards and compliance with the quality, safety and efficacy requirements for regulated

products. In the case of water, for instance, microbiological, physical and chemical tests were initially carried out for analytical processes only. However, we have included pesticide residues and Polyvinyl chloride (PVC) contaminants tests. In the case of imported foods such as fish, milk products and canned food, we included radioactive tests, pesticide residue tests, and Melamine assay for milk products. We have also included tests for toxic Diethylene glycol contaminants for any drug in which Propylene glycol is used as a vehicle. This last test is essential given the striking similarity between Propylene glycol and Diethylene glycol. Diethylene glycol, a toxic antifreeze, has a notorious history of fatality. We encouraged local manufacturers through the application of a differential tariff regime. Registration for foreign Over the Counter (OTC) drugs and processed foods which our local manufacturers have sufficient capacity to manufacture attract the highest tariff, while orphan drugs, which are drugs not produced locally and imported in small quantities, attract low tariff. Drugs for charity or donation are not registered. They are randomly sampled at points of entry and laboratory evaluation is conducted to ensure quality, safety and efficacy.

This new tariff regime encourages foreign investors to establish their manufacturing plants in Nigeria and discourages “briefcase importers”, who are the major fake drug importers. The new tariffs generated the funds we needed to effectively perform our duties. We financed foreign GMP inspections with the revenues, thereby discouraging any form of financial assistance from foreign manufacturers and eliminating any form of conflict of interests. Figures 5 and 6 show a contrast in the funds received from the Government, against our internally generated revenues from 2001 to September 2008. Our capital and overhead costs are funded mostly from internally generated revenue and this is a major achievement.

Establishment of the National Pharmacovigilance Center

In 2004, NAFDAC established the National Pharmacovigilance Centre (NPC) and were admitted as the 74th national centre participating in the WHO Drug Safety Monitoring Programme. So far, the Centre has received 720 Adverse Drug Reaction (ADR) reports. The National Pharmacovigilance Programme is not only for monitoring the safety of drugs, but also serves as an anti-counterfeiting tool, because it tracks counterfeit medicines that are ineffective or toxic through patients’ reports.

From 2001, the Agency, at its own initiative, banned the following drugs: Phenylpropanolamine (PPA) which causes brain haemorrhage, Nimesulide which causes liver cirrhosis and could lead to cancer of the liver, Phenylbutazone which causes blood

dyscrasia, Kava Kava products, multivitamins used by body builders, which are alleged to be toxic to the liver, and Chloramphenicol, used in veterinary products and retained as a toxic residue in meat. These products were banned even before the establishment of the centre.

We knew that several countries had banned or restricted the use of Dipyrone, either in combination with other drugs or as a single substance, due to its reported adverse reactions. Canada, Germany, the UK, the USA and Sweden had banned all Dipyrone preparations. In Sweden, for instance, Dipyrone was first withdrawn in 1974 and re-licensed in 1996 for short-term use in managing acute pain in hospital settings only. Re-licensing was based on a re-calculation of risk from the International Agranulocytosis and Aplastic Aneamia Study (IAAAS) published in 1986. According to the Swedish Medical Product Agency (SMPA), there were 6–7 cases of Agranulocytosis (lowered white blood cell count) in Dipyrone or Metamizole users after the re-licensing and this led to another ban on April 28, 1999. Combination preparations of Dipyrone injections were banned by the German Drug Regulatory Agency after the Chairman of the Drug Committee of the German Medical Association died of anaphylactic shock following the use of a Dipyrone injection in 1997. Dipyrone and all its brands are restricted to post-operative pain, colic pain, cancer pain and migraine in Austria, Belgium, France, Italy, the Netherlands, Spain, Switzerland, South Africa, Russia, Israel and India. Dipyrone is the most popular non-opioid first-line analgesic in Nigeria, Russia, Brazil and other South American and African countries. Due to the popularity of Dipyrone and its related products in Nigeria, we did not want to ban the product without establishing some Adverse Drug Reactions (ADRs). The establishment of NPC created a platform for us to work in partnership with our health professionals in documenting adverse reactions of drugs such as Dipyrone and its related products. The late Professor Olikoye Ransome Kuti, one of Nigeria's most respected health ministers, wanted to ban Dipyrone in the 1980s but opposition by medical doctors forced him to drop the idea.

On November 1, 2004, 14 students of the Federal Government College in Ibusa, Delta State reported at their school clinic with complaint of fever and headache and were treated with medications, which included Maurigin, a brand of Dipyrone injection. By November 3, 2004, two of the students, aged 12 and 14 years, returned to the school clinic with severe pain at the injection sites. The nurse on duty applied Heatol balm on the 14-year-old girl's injection site and a cold compress on the girl who was 12 years old. On November 4, 2004, the condition of the 12-year-old worsened when her right buttock became very hot, swollen, painful and hard to touch. Her left hand was equally swollen. By the next day, the swelling

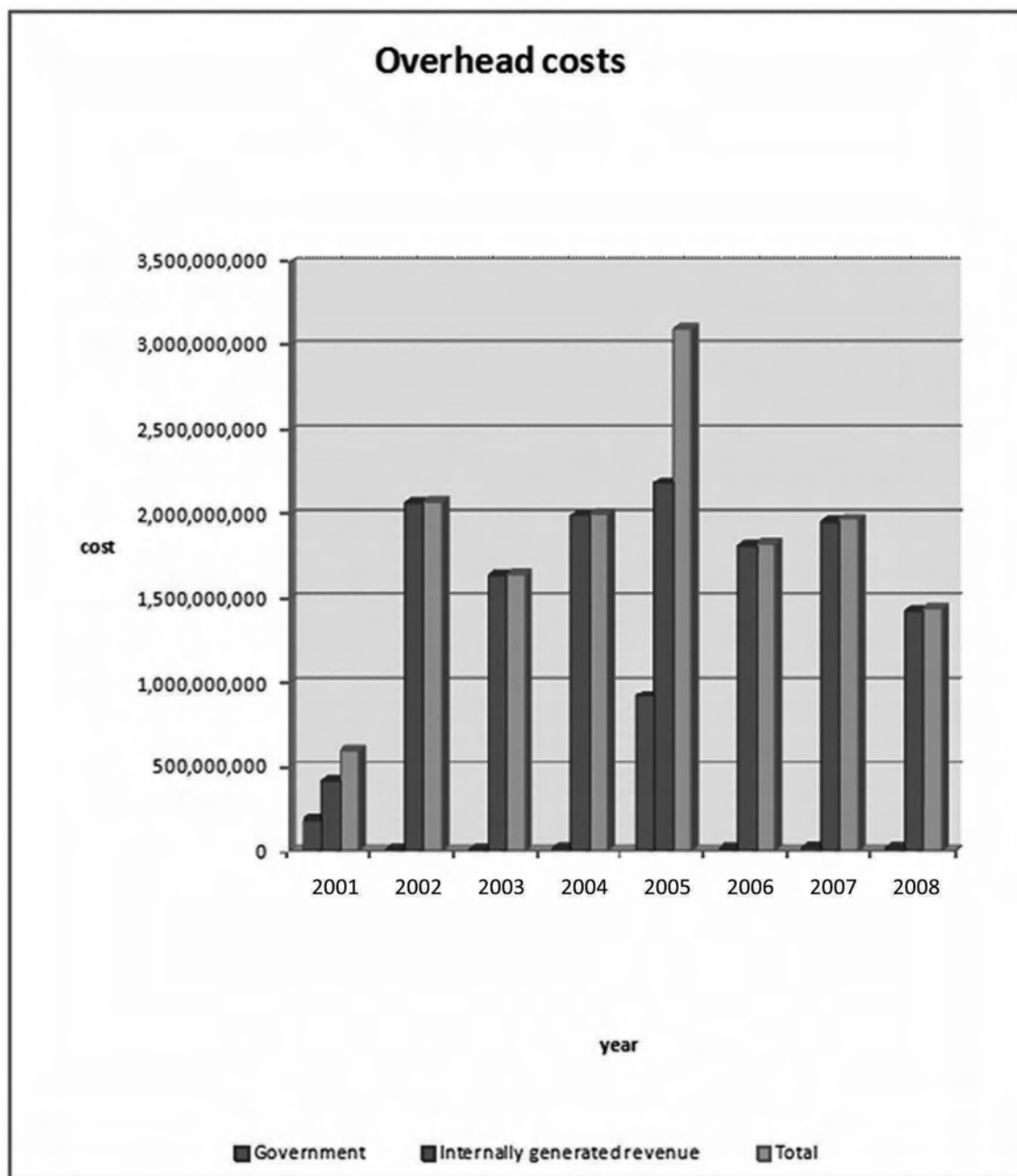


Figure 5: NAFDAC overhead costs (in Naira)

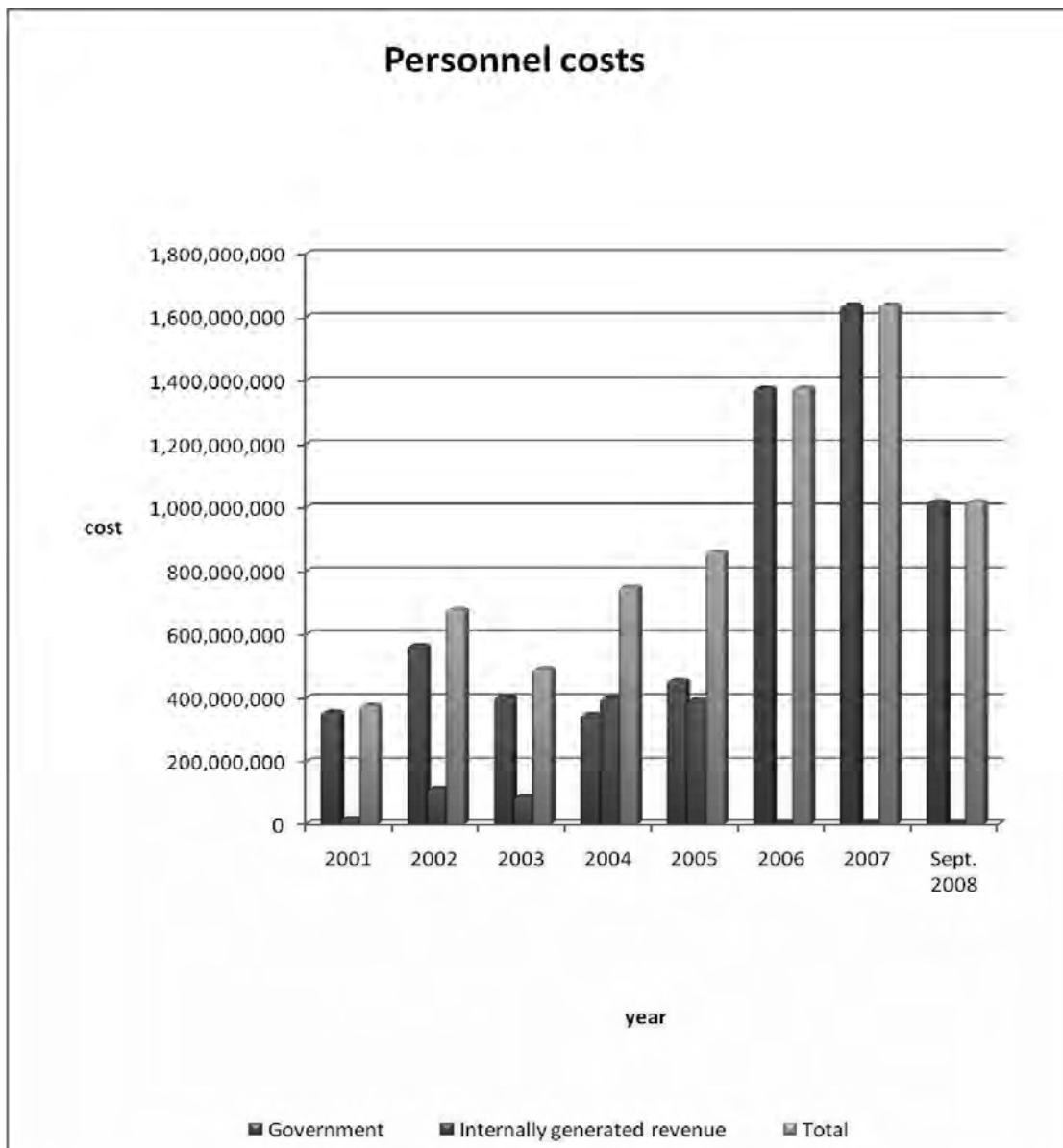


Figure 6: NAFDAC personnel costs (in Naira)

on her left hand had spread to all parts of her body and she was sent home. Her skin began to peel off in large patches on contact. She eventually died on November 6, 2004.

The second student, the 14-year-old, suffered severe tissue damage from the upper left buttock to the back knee. Four surgical excisions of dead skin, subcutaneous fat and gluteal muscle, down to the plane of the sciatic nerve and femur, were carried out in a private

hospital in Onitsha before she was referred to the National Orthopedic Hospital in Enugu state for skin grafting. The last time I saw her, she was in a terminal state.

Investigation by the National Pharmacovigilance Centre (NPC)

Prior to the NPC's investigation, our state office in Asaba had carried out a preliminary investigation into the two cases of Adverse Drug Reactions (ADRs). The particular brand of Dipyrone in question was *Maurigin*, produced by Shanghai Medicinal Corporation, Shanghai, China. Although the brand was not registered by NAFDAC, samples of the injection sent to our laboratory passed quality analysis. The safety profile of the drugs administered to the patients was reviewed by the NPC and found to be of the right quality. This confirmed that the Dipyrone was not counterfeit. The ADR was therefore caused by the intrinsic quality of Dipyrone.

Regulatory and Control Decisions on Dipyrone/Metamizole:

The death of the 12-year-old and the agonising experience of the 14-year-old prompted the following regulatory and control decisions by NAFDAC:

We issued an alert to healthcare professionals and the public on the ban of all brands of Dipyrone or Metamizole.

- i. From September 1, 2005, the manufacture and importation of Dipyrone brands in all dosage forms (injections, tablets and syrups), were prohibited and both active and finished Dipyrone preparations were banned from importation.
- ii. Until January 1, 2006, Dipyrone could only be used under strict medical supervision when other antipyretic or analgesic agents were unsuitable. It was never to be used as a first-line analgesic or antipyretic agent.
- iii. From January 1, 2006, sale and use of such drugs were prohibited in Nigeria.
- iv. Any pharmaceutical company, hospital, clinic or drug retail outlet or market in possession of any brand of Dipyrone from January 1, 2006 would be severely sanctioned.
- v. Any such drugs unused by the end of 2005 were to be surrendered to the nearest NAFDAC office for destruction.

- vi. Members of the public were enjoined to report to the Agency any physician or pharmacist who administered or dispensed Dipyrone or any of its brands after December 31, 2005.

To ascertain that the ban on Dipyrone was strictly complied with, we inspected pharmaceutical companies and hospitals/clinics at the expiration of a three-month grace period, which was allowed to enable sufficient time for medical establishments to find alternative analgesics.

From our experience with Dipyrone, reporting adverse drug reactions enhanced the monitoring of other drugs by NAFDAC, to ensure safe usage, restrict use or ban their use outrightly where necessary. Reporting ADRs could save many patients from suffering the same fate. We urged patients through the media to report ADRs to healthcare providers, who would in turn file the ADR reports with the NPC. Our ADR reporting form, with postage prepaid by NAFDAC, provides for detection of obvious quality defects along with other parameters that aid in the recognition and seizure of counterfeit and substandard drugs. The NPC web page is hosted on our website www.nafdac.gov.ng. We also appealed to all medical practitioners to administer injections only when oral formulations are either not available or unsuitable. We have developed advertisements and jingles to this effect on television and radio. This is essential for a country like Nigeria where most people believe that injections are more efficacious than oral formulations.

In addition to our sustained advertisements in the electronic and print media, we wrote to heads of key establishments in the health sector, such as the Nursing and Midwifery Council of Nigeria and Medical and Dental Council of Nigeria, requesting that they inform their members of the necessity to report every adverse drug reaction to the Pharmacovigilance Center in NAFDAC. This became necessary because the reports we had received up to that point came from the victims or their families and none came from any healthcare provider.

We needed to collaborate speedily and effectively with drug importers to provide alternatives to Dipyrone/Metamizole preparations. Alternative analgesics such as Paracetamol injections and suppositories were needed, especially for patients with severe fever and pains for whom oral medication was not suitable. We dealt with this by granting permission and fast-tracking approvals and waiving all registration fees for 11 companies, five of which were indigenous manufacturers of Novalgin, a popular brand of Dipyrone. The permits allowed the companies

to import Paracetamol injections and suppositories to ensure that our people did not suffer as a result of the Dipyrone ban.

One of my regrets in my over seven and a half years of stewardship in NAFDAC was that we did not ban *Novalgin* earlier. If we had, it would have prevented the death of two Nigerian schoolchildren, in addition to the death of so many other Nigerians whose cases might not have been reported. Every time I reflect on that unfortunate and painful delay, I take consolation in the fact that Dipyrone should have been banned in the early 1980s as it was done in many other countries, but that never happened. However, if we had not acted at the time we did, many more people in the country would have continued to suffer or die from the effect of Dipyrone, which was one of the most popular analgesics then in use in Nigeria.

Access to Ethical Drugs Strictly on Prescription

It has been the practice in Nigeria for ethical drugs to be purchased without prescription. This fuels irrational drug use and sustains counterfeiting. On July 29, 2005, we organised a workshop to educate the relevant stakeholders on the need and our plans to implement strict control of access to ethical drugs. In agreement with all stakeholders, we gave some months of grace before commencing enforcement. In addition to the control of sedatives, which were already being enforced, we started with the enforcement of injectables to be followed by antibiotics.

Developing and Reviewing Operational Guidelines and Standard Operating Procedures

There were no clear-cut guidelines and Standard Operating Procedures (SOPs) for executing regulatory activities prior to April 2001. Each staff member had a different understanding of the procedure for his or her job. There was no correlation of job functions. To streamline the operations of the Directorates nationwide, to reduce delays and abuse of office, we developed various guidelines and SOPs. The guidelines and SOPs list detailed instructions and the expected duration for each activity, thereby institutionalising the processes.

Computerisation of the NAFDAC Product Registration Process

Prior to the inception of the new NAFDAC administration, confirmation of the registration details of NAFDAC registered products was a long and laborious process which required perusing volumes of registration data contained in filing cabinets. Verification of product

registration numbers often required phone calls to Lagos and manual searches through designated files and folders. It therefore became necessary to computerise the system to drastically reduce the registration number verification time. Accordingly, we commissioned the computerisation of the register of NAFDAC products through the development of the NAFDAC Regulated Products Automated Data base (NARPAD). This was achieved through the following stages-

Development of the NAFDAC Regulated Products Automated Database (NARPAD)

(i) The first stage in computerising the registration process was development of the NARPAD system designed to provide touch-type, real-time access to essential details of every product registered by NAFDAC. Furthermore, additional in-built functions such as the registration analysis modules provided instant tabular and graphical summaries pertaining to the number and classification of registered products.

(ii) The second stage was the data capture from the existing records of all registered products and their input into NARPAD. The fields captured included:

- (a) Product name
- (b) NAFDAC registration number
- (c) Approval date
- (d) Product approval expiry date
- (e) Applicant's name and address
- (f) Manufacturer's name and address
- (g) Product presentation and pack size
- (h) State of manufacture
- (i) Country of manufacture
- (j) Superintendent pharmacist

The third stage was real-time generation and utilisation of summaries of registered products in monitoring registration patterns and forecasting future trends. The scope included the following:

- (a) Global summaries – these provide general product registration details for every product in the database.
- (b) Country summaries – the product registration information in these summaries is grouped according to country of manufacture.

- (c) Zonal summaries – provide product registration information grouped according to the geopolitical zones of Nigeria to enhance regional management of registration information.
- (d) State summaries – provide product registration information at the state level to enhance administration at NAFDAC state offices.
- (e) User summaries – provide audit trail information of registered products, grouped according to the officers that entered the data.
- (iv) The fourth stage was utilisation of NARPAD in confirmation of the registration status of registered products across NAFDAC offices, effectively reducing the required confirmation time from days to seconds.
- (v) The fifth stage was the development and commissioning of the NAFDAC Internet Registry Website (www.nafdacregistry.net) from where members of the public could confirm the registration status and details of registered products, at any point in time, from the comfort of their homes.
- (vi) The sixth stage was the enhancement of NARPAD security by the addition of a biometric module, which requires fingerprint login for data entry or modification. This was necessitated when counterfeiters used a NAFDAC staff member to hack into NARPAD and input their unregistered product as registered. These unregistered products have been deleted, the implicated staff member suspended and the companies involved blacklisted. NARPAD is regularly updated with newly registered products.

Conflict Resolution: The NAFDAC Approach

The Agency was inundated with hundreds of registration applications for various regulated products every month. Disagreements between two or more companies over product names, trademarks, package designs and agency rights were common. We received several petitions challenging the status of registered products. However, most of the cases were on disagreements over termination of existing local representation and the appointment of new exclusive agents by foreign manufacturers. The story or background was peculiar to each case, but the result was the same: one party's commercial interest was jeopardised by the creation of new contractual relationships between another party and the manufacturer. We resolved these conflicts by inviting the affected parties to a consultative meeting, to establish the actual cause of the dispute. Through such meetings, we successfully resolved disputes over trademarks, patent claims, products with similar names or look-alikes and revocation of powers of attorney issued by manufacturers to their local representatives.

Trademark Ownership

A trademark is the name or distinctive symbol or device attached to a product. A company or individual usually registers a trademark as an affirmation of that company's or individual's exclusive right to the product.⁵³ Trademarks are national in application and local trademark registration is superior to any international usage or ownership of such trademarks. The application of this rule is illustrated by the following case: when Cullinan Cosmetics Company of Taiwan terminated its agency with Nymph Limited, it was unable to prevent the latter from using the brand name Nymph because of the rule that the first to register a trademark in Nigeria is the prevailing party. The Agency could only reconsider Cullinan's application if it was successful in challenging the use of Nymph by Nymph Limited with the Nigerian Trademarks Registry.

However, in May 2006, there was a Presidential directive that internationally recognised trade names and trademarks should be respected in Nigeria. This was because illegal replication of trade names and trademarks of international companies by Nigerian companies, which had no relationship with such international companies, were discouraging international investment. We have since been complying with this directive. Classical examples of the offshoot of this directive include the following:

Aquafina Table Water – Paramount Trading and Industries Nigeria Limited registered Aquafina table water, a well-known international brand owned by Pepsico Incorporated USA. The registration was cancelled and subsequently registered in favour of 7up Bottling Company Plc, the local representative of Pepsico Inc. in Nigeria.

Great Polo – Mike T.O.C. International Holdings Limited, Onitsha, was in the process of registering Polo, a well known brand by Ralph Lauren. The product was stepped down and the Nigerian company asked to change the name of their product.

Eternity – Cesari International Limited, Lagos, was in the process of registering Eternity, a well-known international brand by Calvin Klein. The registration was stepped down and the company asked to find another name.

In each of the cases, the Nigerian company was allowed to register another name at no extra cost.

Patent Claims

Agents of multinationals and Nigerian companies have been locked in a web of intrigues associated with patent claims. Tyonex Pharmaceuticals Limited, a local pharmaceutical company, applied to NAFDAC to register Amlovas, a product which contains the generic Amlodipine besylate used for the treatment of hypertension, which we duly registered. The drug company Pfizer protested the registration of the product on the grounds that the invention, Amlodipine, and all its pathways, had been patented under Pfizer with the Nigerian Patent and Trademark Registry and that the patent had a life of 20 years, which would expire in April 2007. The patent Laws in Nigeria provide that a person who patents an invention is entitled to the right of exclusive commercial exploitation of that invention for a period of 20 years from the date of filing of the patent. NAFDAC, therefore, in deference to the patent law, deregistered Amlovas, Tyonex's product. Tyonex also brought several applications to NAFDAC in respect of the generic Sildenafil citrate, which Pfizer patented as *Viagra*. We also turned down those applications.

Product Names that Sound Alike

The Agency is often confronted with processing registration of brand names that sound alike. Examples include Ketobid vs. Ketovid, Fleming vs. Flenim, Cipro vs. Cypro, Fungal vs. Fungoral, and so on. To resolve such issues, the Agency considers the time the trademark was registered and when the product's registration application was submitted. Consequently, we have rejected the registration of some products that sound alike. Ketovid was rejected because E. J. Pharmaceuticals Limited had already registered Ketobid; Flenim and Fungal were both declined registration because Medreich Nigeria Limited had previously registered them and Cypro was not accepted for registration because Afrab Chemicals Limited had already registered Cipro 500.

Revocation of Power of Attorney Issued by Manufacturers to their Local Representatives

Another persistent problem we encountered was the revocation of power of attorney issued by the manufacturers to their local representatives, while the product licences obtained by such representatives were still valid. In view of the huge financial expenses incurred in the registration, importation and sale of regulated products, some manufacturers and distributors employ all manner of unscrupulous practices to outwit each other in the bid to maximise profit. They include dishonouring binding powers of attorney and contract manufacturing

agreements. Local agents who spend time and resources to register, advertise and market a product usually get very aggrieved when the manufacturer wants to transfer to another agent, especially when the subsisting agency is still valid. On our part, we normally insist that the manufacturer and the agent keep to the agreement in the power of attorney. For change of local agent, we also require submission of a letter of revocation of power of attorney, letter of appointment of the new local agent and the payment of the stipulated fees. Indiscriminate and frequent change of local representation by foreign manufacturers has been drastically reduced due to our stringent checks.

In cases where aggrieved parties insist on going to court, they end up spending huge sums of money in addition to being in court for several years. One such case involved Cipla, a pharmaceutical company in India. The Indian company issued a power of attorney to EBS Limited, a Nigerian company, giving them exclusive use of a particular brand of their product for a certain period. They subsequently revoked the power of attorney and issued the same rights to Evans Medicals Plc, another Nigerian pharmaceutical company that they considered more effective because they had a better established distribution network. I invited both companies to a meeting. To maintain a conciliatory atmosphere, I excluded all the lawyers on both sides and heard the petitions from the companies' Managing Directors only. From the documents presented, I was able to establish that the right thing to do was to process the registration of the Indian manufacturer's products through their new agent. In addition, I advised the manufacturer to defray the registration expenses incurred by their previous agent. Unfortunately, after the meeting, EBS Limited filed a suit against Evans Medicals Plc and NAFDAC at the Federal High Court Abuja. As I conclude this book, the case has been in court since 2003. However, in most of the dispute resolution instances, the parties do not go to court after our intervention.

Between 2001 and 2007 we successfully resolved 65 out of 80 disputes. Although NAFDAC is neither a judicial body nor an arbitrator, we have amicably resolved conflicts in the area of food and drug registration that could have assumed greater dimensions.

Government Support

We enjoyed tremendous support from the Nigerian Government. The Government's political will, and its support for our efforts, were further demonstrated by new policies approved by the Federal Government. These included an outright ban on the importation of drugs and other regulated products through all land borders from 2001; the designation of Calabar

and Lagos seaports and Murtala Mohammed and Aminu Kano International Airports as exclusive ports of entry for the importation of drugs and pharmaceutical raw materials; and the release of shipping and cargo manifests by the Nigerian Ports Authority (NPA), shipping lines and airlines to NAFDAC inspectors. Our return to the ports in October 2001 yielded tremendous results by way of increased level of seizures of substandard regulated products and sanctions against offending importers, resulting in the return of some level of sanity in the importation and distribution of drugs and other regulated products. Before October 2001, NAFDAC officials were not in the ports for routine inspection of imported products.

In addition to the tremendous support by government, the support enjoyed by NAFDAC from the Nigerian public was unprecedented in the history of Nigeria.

CHAPTER 10

STRATEGY III: ENGAGING STAKEHOLDERS

Quite early on the job, I saw the need to take my message to the public, following the success we achieved with the pure water enlightenment campaign. It was clear to me that this strategy would help us sensitise the public to the high incidence of counterfeit medicines and engage the various stakeholders in frank and open discussions on the magnitude of the problem of counterfeit medicines and other substandard regulated products, with a view to finding sustainable solutions which would be acceptable to all.

We employed the strategy of public enlightenment campaigns through workshops, seminars, publications, grassroots sensitisation campaigns and consultative meetings with stakeholders both at national and international levels.

Public Enlightenment Campaign

Most Nigerians were unaware of their right to good quality regulated products. The manufacturers and distributors of fake and substandard regulated products cashed in on the ignorance of the public and our regulatory inadequacies to dump unsafe products in Nigeria. Consequently, we embarked on massive enlightenment campaigns using dialogue, education and persuasion, to sensitise Nigerians on the dangers of fake and counterfeit regulated products. This strategy addressed the fundamental issue at stake, which is behavioural change. We involved various stakeholders within and outside Nigeria, ranging from pharmacists and other health practitioners to professional bodies, patent medicine dealers, traditional medicine practitioners, manufacturers, importers and exporters of NAFDAC regulated products, chemical marketers, bakers and hotel and fast-food restaurant operators. Others included government agencies, regulatory agencies, journalists, the judiciary, road transport employers and operators, financial institutions, educational institutions, the maritime industry, freight forwarding and clearing agents, printers, advertising practitioners, the diplomatic community, NGOs, youth groups, politicians, traditional rulers, religious leaders and groups, business associations, market associations and consumers. The print and electronic media were extensively used in the campaign.

We adopted public enlightenment as a strategy in the framework of information, education and communication, (IEC). The result-oriented campaigns, were our most effective approach towards eradicating fake products. They were designed to inform consumers, thereby empowering them to exercise their rights to good quality regulated products. We encouraged them to cultivate new habits such as scrutinising labels of regulated products for name and content of the product, NAFDAC registration number, batch number, manufacturing date, expiry or “Best Before” date, manufacturers’ full name and address and any other relevant information.

We increased our staff strength at the Food and Drug Information Centre (FDIC) and improved our information technology capacity to disseminate information on our activities to the public. Important alert notices of identified fake products were disseminated through print and electronic media, the NAFDAC website and quarterly bulletin and bi-monthly newspaper publications. We also disseminated information using billboards, jingles, announcements and advertisements in the media. Grassroots mobilisation campaigns for the rural areas kicked off in February 2005 in Kano State, and were replicated nationwide. We produced different kinds of publications, handbills and posters, both in English and in other local languages, to reach our target audience.

Workshops and Seminars

The workshops and seminars organised for various stakeholders were interactive in nature and encouraged contribution of ideas from participants. In this regard, we have traversed the length and breadth of Nigeria and covered diverse subject matters. The following are a few examples of the workshops and seminars we organised for some key stakeholders:

Producers of Packaged Water and Other Water-Based Drinks

The production of packaged water popularly called pure water grew rapidly in Nigeria because of the simple techniques involved in its production. The water is packaged in low-density polyethylene sachets to make it cheaper and more readily available for the lower income segment of the population. The production has low capital requirements. The abundance of free water sources in Nigeria, coupled with the high unemployment rate, the tropical heat, high demand for water by the over 140 million-strong population and lack of potable water in many areas, made the production of pure water an attractive venture.

By 2001, very few brands of packaged water were certified by NAFDAC and a large number were contaminated. The general expectation of the public was that NAFDAC should arrest

the illegal producers, close their pure water factories and prosecute them, to raise standards in packaged water production in Nigeria. However, we needed to balance Nigerians' rights to potable water against the high unemployment rate and the desire by pure water producers to earn an honest living. We also appreciated the fact that most of these illegal pure water producers were ignorant of the health hazards of poorly produced pure water and would do better if they were properly guided. A classic case was encountered in May 2001, when a young man was caught refilling discarded empty plastic bottles of a well-known brand of bottled water with tap water from a dirty bucket in a filthy environment. His sealing method was rather clever. He used a red-hot knife heated on a kerosene stove for the sealing. It was difficult to distinguish between his water and the original. When questioned, his reply was, "I no dey kill anybody, na the water wey I dey drink I dey sell." What he was actually saying is that "I am not out to kill anybody. The water I sell is the same water that I drink." This was ignorance at its peak. By Nigerian law, he should have been prosecuted and made to pay a minimum fine, after which he could go back to the same business. Contrary to his expectations of being punished, I explained the consequences of his action and issued a serious warning. He was remorseful and pledged never to indulge in such illegal acts. This incident and other similar cases coupled with pressure from the press necessitated our nationwide workshops for pure water producers.

We conducted the first workshop in Lagos, on June 21, 2001, and subsequently organised similar workshops in all the 36 states of the Federation and Abuja, the Federal Capital Territory. The workshops were for producers of registered packaged water and other water-based drinks such as yogurt, milk and juices. Unregistered producers of these products and intending producers were also invited. A total of 10,636 participants attended the workshops. Since most of the water producers were in the low-income group, participation at the workshops was free.

The participants were educated on the health implications of producing unwholesome packaged water. We taught them standard procedures for producing the right quality of pure water and showed them simple and affordable equipment that could be used. Our registration procedures and guidelines were streamlined to facilitate the registration of pure water and other water-based products. We offered free consultancy services for pre-production and production procedures, to enable prospective producers to start on the right footing. We reassured them that, even if any of their products failed laboratory analysis, we would come to their production plants and offer them the necessary assistance, at no cost.

As a follow-up to the workshop, we wrote to all hotels and restaurants in October 2001, asking them to crush or puncture empty water bottles in their premises, to prevent them from being re-used by the producers of fake packaged water.

By December 2001, we had gained the confidence of pure water producers, to the extent that they were very eager to comply with our regulations. The compliance was unprecedented. On April 29, 2002, we invited pure water producers who had difficulties in registering their products to come forward with their problems to designated centres for assistance (Appendix 6a).

By August 2003, we had analysed 3,844 samples of sachet water and 1,307 samples of bottled water in our laboratories nationwide. In the same period, we registered 1,579 brands of sachet water and 585 brands of bottled water. In all, 2,164 brands were registered in this period, compared to 423 brands of both sachet and bottled water registered from 1994 to 2000. Reports from villages, schools and other communal places indicate that the public caught the pure water awareness “bug”. Non-literate Nigerians now ask people who can read to help them check for the NAFDAC number on pure water sachets before purchase.

Between May and July 2003, we embarked on post-marketing surveillance of pure water brands in circulation. Our aim was to ensure that the producers maintained the quality we originally approved, determine how many unregistered pure water brands were in circulation and ascertain their quality. The result of this survey was very distressing. Out of the 1,000 brands of pure water tested, we observed that over 95 per cent were contaminated with either microorganisms or chemicals. We decided to further investigate this issue of contamination by a process of elimination, tracing the batches of the unwholesome samples of pure water to the plants where they were produced and confirming that the samples were actually produced in those factories by matching the batch numbers. We collected fresh samples of the products from their production lines and re-analysed them. The new results indicated that most of the plants were still producing the right quality of pure water. This was rather puzzling. To solve this mystery, we randomly collected fresh samples from several factories and performed accelerated stability tests, to determine the rate of degeneration over time, at increasing temperatures. We discovered that, even with a food grade low-density polyethylene bag, which is certified by NAFDAC for packaging sachet water, the water degenerated in quality after two months. By using this systematic method, we confirmed that most of our pure water producers were not fraudulent and we were pleased with that. After discussions with executives of the National Association of Table Water Producers

(NATWAP), we issued public notices on radio and television and in newspapers, directing pure water producers to limit the stated shelf life of their products to two months. We also used the media to advise the public to avoid purchasing pure water with a longer shelf life. We allowed the producers three months to adapt to the new regulations and began enforcement on January 2, 2004 (Appendix 6b). Through such advertorials, we successfully conveyed to the public the information that pure water would be unsafe if consumed after two months from its date of production. Furthermore, we organised trainings on Hazard Analysis and Critical Control Point (HACCP) for the producers of packaged water. We believe that the introduction of HACCP to their Quality Assurance System will improve the quality of manufactured products in the food, water and other related industries.

Patent and Proprietary Medicine Dealers

Patent and Proprietary Medicine Dealers (PPMD) have been in the business of drug distribution and sale for many decades, with some as third-generation drug sellers. Most of them are not formally educated, but have simply learnt their skills on the job. They mostly obtain their drug supplies from illegal wholesale drug markets. However, we regard them as an important group because of the scope of their operation. They render services to people in remote villages that otherwise have no access to pharmacists or medical doctors. Unfortunately, they also supply drugs to street hawkers, who sell them on the streets and aboard commercial buses. Their stores, commonly called patent medicine stores, were not registered because of a legal tussle with the Pharmaceutical Society of Nigeria (PSN). This meant that the activities of the members of the PPMD were not regulated.

We recognised the importance of this group in the drug distribution system and the need to work with them. We knew that the PPMD was an invaluable ally for penetrating the network of importers and dealers in counterfeit medicines and we wanted to earn their trust and confidence. Consequently, we organised interactive workshops, starting with a national workshop in Abuja, the Federal Capital Territory, on October 22, 2001. This was replicated in every state of the Federation. A total of 34,784 participants attended the workshops and each paid a subsidised fee of ₦500 (US\$4.35), to cover the cost of workshop materials, lunch and drinks.

We started each workshop with a song to liven up the atmosphere. The song goes thus:

1. We have said No to selling fake drug (Thrice).

No going back, no turning back (Twice).

2. We have said No to buying fake drug (Thrice).

No going back, no turning back (Twice).

The song was adapted from a Christian song, which is popular in Nigeria. This song flashed through my mind on July 14, 2001, on my way to Onitsha, one of the major drug markets, for the first counterfeit products destruction exercise. The song caught on like wildfire and was sung like an anthem in the drug markets.

We held the patent medicine workshops amidst criticism and bitter opposition from my colleagues, the members of the Pharmaceutical Society of Nigeria (PSN). They argued that since patent medicine dealers were unregistered, they were illegal dispensers of medicines and should not be acknowledged by any regulatory authority. The PSN and the PPMD had been in contention over the right of the PPMD to exist and deal in pharmaceutical products. The pharmacists feared that NAFDAC's romance with patent medicine dealers would lend credence to their illegal practice and might eventually lead to their being licensed. Pharmacists unleashed a most contentious tirade in the press against NAFDAC and my person. We ignored all these distractions, as we were sure that we were on the right track. Licensed or not, this group controlled a good chunk of Nigeria's drug distribution network and we needed their cooperation to succeed in our mission to eradicate counterfeit medicines. We just had to find ways of stopping them from re-labelling counterfeit medicines, storing and handling drugs improperly and indulging in other nefarious and unethical practices. We had to enlighten them on the dangers of re-labelling drugs to extend their shelf life beyond their expiry dates and the fact that improper storage of medicines leads to degeneration and loss of potency. We educated the group on the purpose of expiry dates and the need to store their thermolabile drugs in fridges and non-thermolabile drugs in air-conditioned rooms, or at least at room temperature. They learnt that the rate of degeneration of any drug is directly proportional to temperature and that at temperatures higher than 25°C (the temperature used in determining the expiry date), drugs degenerate faster than normal. This was crucial as Nigeria is in the tropics, with some states recording temperatures up to 40°C. The workshops further dealt with the health and socio-economic implications of fake and

counterfeit drugs and reasons why such damnable and destructive activities should neither be aided nor abetted. The participants found the workshops very enlightening.

In the course of the workshops, we solicited their assistance in fishing out the fake drug importers and dealers in their midst. We also used the opportunity to appeal to the conscience of the people involved in the importation and distribution of fake and counterfeit drugs, hoping to persuade them to discontinue such wicked practices.

The members of the PPMD turned out to be amongst our strongest supporters in the war against counterfeit medicines. The support and cooperation of the Chairman and Executive Members of the Onitsha branch of the PPMD enabled us to apprehend Chief Marcel Nnakwe, the biggest fake drug counterfeiter in Nigeria at the time. With their assistance, we located his warehouses and got him to sign a letter of forfeiture with which we seized and destroyed his counterfeit medicine. We were able to accomplish this feat despite several court orders pending against NAFDAC at his instigation. He tendered a public apology to Nigerians for dealing in counterfeit medicines for over 20 years and wrote an undertaking that he would not deal in counterfeit medicines any longer (Appendices 7 and 8). From 1996–8, Chief Nnakwe had several consignments of drugs seized by NAFDAC. He also had four cases pending in court. His public apology was therefore unprecedented. It was the first time in Nigeria's history that a criminal of such stature had publicly apologised to the nation for his criminal acts.

The PPMD is now a self-regulating association, which is officially licensed by the Pharmacists Council of Nigeria (PCN) to carry out their drug distribution business legally. Their active cooperation enabled us to find, seize and destroy over ₦850 million (US\$7.39million) worth of drugs in Onitsha, in July 2001 and over ₦1 billion (US\$8.70 million) worth of drugs in Lagos, in October 2001. Some of these drugs were voluntarily forfeited by repentant traders, while the rest were confiscated when we acted on tip-offs.

National Union of Road Transport Workers

Street drug hawkers use motor parks or garages as their stores, often taking off from one motor park and ending up at another. We therefore decided to involve the National Union of Road Transport Workers (NURTW) in our crusade. Most of the drugs hawked were either fake or genuine but degenerated due to the intense tropical heat. Although the NURTW are popularly called “touts”, some of their members are responsible citizens. Many of them scout for passengers for buses due to lack of job opportunities. We had the first workshop

for the NURTW in Lagos on November 15, 2001 and subsequently carried out workshops for them in the 36 states of the Federation and Abuja. 900 participants attended the workshops and received lunch and workshop materials free of charge. We achieved rather limited success with this group.

National Association of Road Transport Owners (NARTO)

The National Association of Road Transport Owners (NARTO) is a union of owners of commercial buses and vehicles in Nigeria. Drugs are often hawked in their vehicles. We believed that it was impractical to chase down every drug seller on board commercial buses, especially as we did not have a sufficient workforce to do this. Nigeria is vast, having the ninth largest population in the world. The large number of commercial buses plying the roads all over the country made it impossible for us to attempt this. We believed that the bus owners and their drivers were strategically positioned to stop the sale of drugs on buses because they have control over their vehicles. If a driver knew that he might lose his job by allowing hawkers to sell drugs in his bus, he would not allow them. We therefore decided to organise a workshop for the members of NARTO. The workshop commenced in Lagos on November 14, 2001, with 450 bus owners in attendance. It was replicated in all the 36 states of the Federation and Abuja, the Federal Capital Territory. The workshop materials and lunch were provided free of charge.

Following our passionate appeal, they pledged their support and requested that we report erring drivers or buses to the union's head office. They promised that such a driver would be summarily dismissed. Many of them kept their pledge. Thereafter, we wrote to the major bus transport company owners who did not attend the workshop to inform them of the decisions and agreements reached. The Young Shall Grow Motors for instance, directed all its drivers to prohibit the sale of NAFDAC regulated products on board their vehicles. We also issued a press release directed at commercial bus owners, reiterating our position on the sale of drugs aboard their vehicles, reminding them of their Association's pledge and soliciting their continued support (Appendix 9). Furthermore, we issued a guideline stating that any commercial bus driver that allow the sale of drugs onboard his or her bus would have the journey terminated, the passengers forced to disembark and the vehicle taken to the nearest NAFDAC office. This nuisance factor was designed to elicit the support of the passengers.

Due to the immense awareness our enlightenment campaigns created about the sale of drugs on board buses and with the advent of mobile telephones, the public often called in with information whenever they came across a defaulter.

Drug Importers

Drug importers are key stakeholders in the fake and counterfeit drugs business. By law, foreign companies must have local agents to import drugs into Nigeria. On April 3, 2002, about 450 participants attended the workshop we organised for drug importers in Lagos. It was also an opportunity for us to introduce our new guidelines for stopping fake drug importation. The workshop was interactive to encourage the flow of ideas from the participants and obtain their commitment to our cause. We also explained the reasons for revising our registration tariffs.

Licensed Freight Forwarders and Clearing Agents

The workshop with this group of stakeholders took place in Lagos on April 4, 2002, with 250 participants in attendance. The event was substantially subsidised by the Agency. We also organised a similar workshop for the agents in Port Harcourt, Nigeria's second port city. Our message to the clearing agents mirrored that for drug importers. We encouraged them to provide us with information on suspected non-registered or expired drugs and other substandard regulated products imported into Nigeria. They were also instructed to ensure that no drug product is cleared without NAFDAC's release stamp.

Sensitization and Awareness Campaign for Pharmacists

In Nigeria, drug markets are illegal because trained professionals do not operate them and storage conditions are not conducive to the stability of drugs. In order to provide a viable alternative to the illegal drug markets, we developed the Zonal Drug Distribution Centres concept, referred to as Drug Mart. We were working with the National Assembly to appropriate money for its construction when some pharmacists got together to oppose it. We believed that the opposition was based on lack of full understanding of our concept of the Drug Mart. Pharmacists, being our major stakeholders, were therefore invited to a meeting where we could explain the concept and solicit their support for it. The idea was to have a wholesale facility for drug distribution in every geopolitical zone of the country. The facilities would be conducive to drug storage and supervised by pharmacists.

In August 2001, at the Oshodi Laboratory Complex, we held a special meeting with all the Technical groups of the PSN, specifically to explain the concept of Drug Mart. During this meeting, our consulting architect showed the pharmacists the proposed drawings and explained the design. All the technical arms of the PSN also contributed.

At another meeting, which was a major nationwide sensitisation workshop held for pharmacists, representatives attended from all technical groups of the PSN from all the states of the Federation. The title of my speech was, “Let Us Join Hands and Build Together for The Health of Our People: An Appeal to All Pharmacists.” We also explained our regulatory practices, vision, challenges and plan of action. I passionately appealed for their support and cooperation. The workshop ended on a very friendly note. We went away, believing that we had effectively sold the idea of the Drug Mart and that the PSN understood and accepted the concept. Surprisingly, after the meeting, opposition to the Drug Mart intensified in the media. In spite of this, the National Assembly, cognizant of the attendant benefits and seeing it as a viable alternative to our present chaotic drug distribution system, approved the establishment of the Drug Mart and appropriated funds for it. However, when the opposition to the Drug Mart continued, we felt it was beginning to be a distraction and decided to set it aside. This decision was communicated to the National Assembly who did not object to my decision to drop the proposal.

However, the fact that I did not pursue the Drug Mart initiative to fruition irrespective of the opposition from pharmacists remains one of my greatest regrets. Since then I have been discussing with private companies, the possibility of setting up wholesale drug outfits, which would provide a regulated wholesale drug environment for hospitals and drug retailers.

Traditional Medicine Practitioners (TMPs)

Our first step towards regulating the herbal medicine industry was to request that all Traditional Medicine Practitioners (TMPs) come forward and register their products (Appendix 10a). Statutorily all drugs, whether orthodox or not, must be certified by NAFDAC before they can be advertised, distributed, sold or used. Every drug product advertisement must be screened and approved by the Agency, with permits issued before the media can publish it. TMPs did not respect this directive. Hence, the various groups of herbal medicine practitioners were invited to interactive meetings prior to developing guidelines for the registration and advertisement of their products. Furthermore, workshops were scheduled to build upon the success of the interactive session. The first national workshop was held in Lagos on July 31, 2002, followed by zonal workshops in the six political zones of the Federation. An overwhelming number of people attended the events, occasioned by the fact that attendance was free.

In attendance were all sorts of traditional health practitioners ranging from voodoo practitioners, traditional spirit mediums who evoke the spirits of the dead and herbalists, to magicians and educated alternative medicine doctors. The number of people who turned up gladdened us, but a lot of them did not understand the reason for the workshop. Some had come in anticipation that the gathering was a sort of national circus to display their magical prowess. A particular snake charmer brought different kinds of snakes to the Northern workshop held in Kaduna to perform snake dances. In any case, the workshop sessions began and the participants were educated on the reason for the event and the focus on the Agency's plans to control medication extracted from herbs and plant parts. At the pre-workshop meetings, we arrived at a fee of ₦10,000 (US\$87) for the registration of herbal products produced by small-scale herbal practitioners and ₦20,000 (US\$174) for large-scale operators. We also agreed on the following:

- (a) The guidelines for the registration, listing, labelling and advertisement of herbal medicines should be simplified to encourage compliance (Appendix 10b).
- (b) NAFDAC should not divulge the secret contents of the herbal medicines where practicable. However, the herbal practitioners were informed that the patent office and Nigeria's patent laws exist to protect their inventions.
- (c) All practitioners should be encouraged to join self-regulating professional associations.

We also wrote to the print and electronic media and other media practitioners in the country soliciting their assistance to ensure that only adverts with a NAFDAC advert permit are aired by their media. We educated them on the Drug Products Advertisement Regulations of 1995, which seek to control the advertisement of both prescription and over-the-counter drugs, including herbal products. The regulation also prohibits the following:

- (1) Any false or misleading information.
- (2) Half-truths, inadequate qualification and limitations regarding safety or effectiveness of the drug.
- (3) Vague, unsubstantiated statements or suggestions of superiority over other competing drugs.
- (4) Any false impression that the advertised drug is for universal cure or should be regarded as a more effective and safer alternative to other related drugs (Appendix 10c).

In recognition of the long usage of herbal medicines by our people and in line with the WHO recommendations concerning long-documented history of their safe use in a locality, coupled with the positive effects of placebos on some patients, we test only for safety and quality, and not efficacy, before authorising them for use. For safety and quality, we perform tests for acute toxicity, microbial load, pathogenic bacteria, heavy metals and extraneous matter such as filth and dirt. Registration of herbal products is classified as listing which is valid for two years. Every listed herbal product is required to bear a disclaimer stating “these claims have not been evaluated by NAFDAC”. If a herbal product manufacturer wants to drop this disclaimer, the product must undergo a successful clinical trial. As I conclude this book, no herbal medicine produced or imported into Nigeria has qualified to have this disclaimer dropped.

Following the workshops, 876 herbal medicines have been listed, out of which 519 are locally produced, while 357 are imported. Bogus claims and unauthorised advertisements of herbal medicines have drastically reduced. I paid a courtesy call on the then Governor of Edo State, Chief Lucky Igbinedion, during which I solicited his support in our campaign against deceitful and bogus advertisement of herbal medicines. In response to my appeal, he immediately directed that no radio, television or newspaper in Edo State should advertise any herbal medicine without clearance from NAFDAC (Appendix 10d). Encouraged by this outing, I wrote to all State Governors in the country soliciting their support in banning the unauthorised advertisement of herbal medicines in their state-controlled media (Appendix 10e). I was encouraged by the positive response from Dr Olusegun Agagu, the then Governor of Ondo State, who immediately banned the unauthorised advertisement of herbal medicines in his state.

Workshop for Media Practitioners

There were all sorts of advertisements in the print and electronic media on herbal medicines, most of which were bogus and misleading. We wrote to all media houses, requesting that they desist from publishing or airing advertisements for any herbal medicine without a NAFDAC advert permit. We also gave them a time limit, and we put up advertorials to this effect. Two media houses replied requesting that we give them more time to implement the directive because the adverts had already been paid for to cover a specific period. Despite our letters and advertisements plus the support of the National Broadcasting Commission in this regard, there was low compliance in both print and electronic media. We therefore organised a national workshop in Lagos for all journalists on August 12, 2003. The key

objective of the workshop was to get the support of the media in enforcing the stoppage of unauthorised advertisements for drugs and bogus claims of cure, especially by herbal practitioners. We reiterated our earlier appeal that all media houses should cite a NAFDAC advert permit before airing or publishing any drug or food advertisement. We also seized the opportunity to sensitise them on the need to support NAFDAC in the fight against counterfeit medicines, unwholesome food and other substandard regulated products. At the end of the workshop, they agreed to cooperate with us on the advert issue and reaffirmed their commitment to the war against counterfeit medicines.

Unfortunately, even as I conclude this book, I feel very sad that one of the very few areas where we have not recorded a high level of success is in the regulation of herbal medicines advertisements.

Chief Executives and Heads of Foreign Exchange Departments of Banks

Most drug importers process their import documents and obtain foreign exchange from commercial banks. The banks are therefore strategically positioned to be effective intervention partners in the war against counterfeit medicines. They can ensure that documents for importation of drugs are processed only upon presentation of evidence that the drugs to be imported are duly registered by NAFDAC.

After Chief Marcel Nnakwe's public confession, the Managing Director of now defunct Manny Bank, Dr Jonah Ezeikpe, refused to open letters of credit for him. I was thrilled when he made this known to me and it accentuated the importance of working closely with the banks to frustrate the fake drug importers. When I mentioned Dr Ezeikpe's patriotic act to Mr Tony Elumelu, the Managing Director of Standard Trust Bank at the time, he agreed to sponsor a workshop for banks and other financial institutions to co-opt them as partners in the war. The workshop took place on January 21, 2003 and was attended by 400 participants, most of them managing directors and heads of foreign exchange units of banks all over Nigeria. It followed the pattern of other stakeholder workshops we had organised. Bankers were to insist on NAFDAC clearance before processing any letters of credit for the importation of drugs or pharmaceutical raw materials. They agreed to comply with this requirement and it was subsequently adopted by the Central Bank of Nigeria (CBN). Nigerian banks now require NAFDAC clearance before processing foreign exchange and international financial instruments for the importation of drugs and pharmaceutical raw materials. This chain of events evolved into an effective government policy, which turned out to be one of

our greatest achievements in our efforts to deter the criminals involved in the fake drug trade.

Cosmetics Manufacturers and Ethics Association of Nigeria (COSMEAN)

A workshop for producers and importers of cosmetic products took place in Lagos on August 1, 2002 with 960 participants in attendance. They were sensitised on the health and socio-economic impact of counterfeit products, especially in the area of cosmetics containing banned chemicals. We circulated our new guidelines on GMP certification and distributed the list of deleterious and harmful substances. At the workshop, we insisted that cosmetics should not contain any Hydroquinone. However, we have modified our position and now permit a limit of 2 per cent, which is in line with the globally accepted standard. This revision was, as usual, well publicised.

The Agrochemical Sector

We received alarming reports of hospitalisation of hundreds of people, mostly school children, and the deaths of a few, across the country, especially in Cross River and Gombe States following their consumption of black-eye beans. Our investigation revealed that the beans were contaminated with Endosulfan and Lindane. Lindane popularly known as Gamalin 20 is a banned pesticide in Nigeria. To address this crisis, we organised sensitisation workshops, in collaboration with CropLife Nigeria, which represents the plant science industry in Nigeria. The workshops, entitled “Safe and Responsible Use of Agrochemicals and Other Pesticides”, were held in Gombe for the North-East Zone and Calabar, for the South-South Zone on May 12, 2008 and June 9, 2008 respectively. At the workshop, we trained the grain merchants on the proper method of applying pesticides. They were taught to apply the pesticides on the bags containing the grains and on the floors and walls of the storage facilities, as against applying the pesticides directly to the grains. We followed this up by banning all pesticides that could only be used by mixing with the grains. The poisoning of the beans was actually caused by excessive application of the pesticides, coupled with failure to comply with the standard withholding time. The workshops were well attended and we planned to replicate them in the other geopolitical zones of Nigeria.

Bakers and Flour Millers

The major challenge for bakeries and flour millers in Nigeria is the quality of baking flour. As a result of wide variations in the composition of baking flour, various treatments and

conditioning agents, such as dough enhancers, are added to flour for strength during mixing and moulding, to increase loaf volume and to improve its texture.

The use of Potassium bromate, popularly called tablet, has been a common practice among flour millers and bakers throughout the world. It is cheap and probably the most efficient oxidising agent. In the early 1990s, the Food and Agriculture Organization (FAO) banned Potassium bromate because of its implication in cancer, kidney failure, deafness, breakdown of vitamins in bread and other deleterious effects in humans. However, Nigerian bakers continued to use this harmful substance as a bread enhancer.

Acting on tip-offs by bakery workers on the rampant use of Potassium bromate in the industry, we conducted a random survey of bakeries in Nigeria and found that over 95 per cent were using Potassium bromate as a dough enhancer. Only a few bakers used the recommended Vitamin C and enzymes to enhance bread, and even fewer complied with Vitamin A fortification requirements for baking flour. We regarded this as mass poisoning, since bread is a staple food for most Nigerians. We therefore organised enlightenment campaigns for bakers in all the states of the Federation.

Following these enlightenment campaigns, we organised a national workshop in Lagos on March 4, 2003, for over 1,000 bakers. During the workshop, we provided the participants with a list of dough enhancers that are approved and registered by NAFDAC. We also provided them with information on all possible alternatives to Potassium bromate, particularly Vitamin C and the appropriate enzymes. After the workshop, bakers were allowed a two-month moratorium to comply with our ban on bromate. We published a nationwide red alert on November 8, 2002 against the use of Potassium bromate in bread (Appendix 11). Unfortunately, after the moratorium period and in spite of our repeated warnings, we discovered that many bakers were still using Potassium bromate. In order to mitigate the persistent risk to public health, I authorised a nationwide action of removal and destruction of all Potassium bromate-contaminated bread. During the exercise, millions of loaves of bread were destroyed and many bakeries were closed down. At the end of the exercise, we initiated another round of public enlightenment campaigns and held workshops with the bakers on the need for them to comply with the Agency's directive and avoid the use of Potassium bromate in bread. At these workshops also, we taught the bakers the best practices in bread handling including ensuring that bread for delivery to retailers is appropriately wrapped.

However, in September 2005, we received reports that some bakers were still using Potassium bromate. We conducted a nationwide survey to determine the presence or otherwise of

Potassium bromate in bread. Some 64 bakeries were found to be culpable, including that of an ex-president's wife. The bakeries were immediately closed down. I received a series of calls from different parts of the country, with each caller worried about the closure. I took time to explain that we did not have double standards when applying sanctions. During the same period, the only bakery in my husband's village was closed down for the same reason and the villagers were outraged. A distant relative of my husband went to the extent of calling me and saying in Igbo: "Agu adi eli agu ibe ya; nkita adi ata nkita ibe ya; agwo adi ata agwo ibe ya; mana itago ndi nkegi! Ilusia olua, gi na Obasanjo bili na Abuja," which literally translates as: "A lion does not eat a fellow lion; a dog does not bite a fellow dog; and a snake does not bite a fellow snake; but you have bitten your own people! When you are done with that job, stay back in Abuja with Obasanjo." In other words, make sure you do not return to our community. We eventually decided in a management meeting to re-open the 64 bakeries, as we were also interested in the growth of our local industries. However, we wrote to each bakery, warning them to stop the use of Potassium bromate as a dough enhancer. Some members of the press started asking me why the "big man's" bakery was re-opened and I always retorted: "Why should it remain closed when others have been re-opened? Because of its ownership?"

We carried out routine street seizures and the destruction of bread that had no labels, or labels without the full addresses of the bakeries indicated on them. Most of these unwrapped loaves are heavily dosed with Potassium bromate and their producers cannot be traced. We went on to register bread from all bakeries nationwide, issuing the bakers with a NAFDAC registration number for a period of three months, with a view to certifying compliant brands and continuously tracking the quality of each brand. We eventually had to relax the period to allow sufficient time for our officers to reach bakeries in remote villages. The NAFDAC bread registration exercise was done at no cost to the bakers.

The use of Potassium bromate by Nigerian bakers has dropped drastically, from over 95 per cent of all bakers in 2001, to less than 0.001 per cent in 2007. Bakers are now adding Bromate-free on the labels of their bread and the public is also demanding to know the contents of the bread they buy. Very few recalcitrant bakers are fined and on second offence, their bakeries are shut down. We tried prosecution of offenders at the early stages of enforcement, but found it protracted, ineffective and non-deterrent.

Reaching out to the Youth

In 2002, we instituted an annual essay competition for Nigerian High School children. We gave out cash prizes to the winners while computers, television sets, microscopes and encyclopedias were given to their schools at state, zonal and national levels. We also established Consumer Safety Clubs in the schools as a platform for interacting with the students, to inculcate in them a culture of quality consciousness.

The Green Pages

In our concerted efforts to find new ways to rid Nigeria of unwholesome regulated products, we engaged in Public–Private Partnership (PPP) with Zane Designs Limited. We initiated the partnership in the last quarter of 2003 with the signing of an agreement between NAFDAC and Zane. The company was to compile, edit and present in user-friendly form, the NAFDAC Green Pages, a listing of all NAFDAC registered products in a multimedia format. The publications fill the gaps perceived in the use of government gazettes, which contain listings of registered products in forms that are not user-friendly. The NAFDAC Green Pages provide opportunities for the advertisement of registered products, offering the marketing authorisation holders platforms to showcase their products to the consuming public and allowing them to differentiate their genuine products from fakes and counterfeits. Furthermore, in villages and rural areas where there is erratic power supply and sometimes lack of Internet access, the NAFDAC Green Pages may be the only authentic source of information on genuine NAFDAC registered products.

The introduction of the NAFDAC Green Pages opened a new vista in our enlightenment campaigns. The publications are clear and verifiable sources of information, providing accurate data on all registered products, along with the authentic source of each product. NAFDAC Green Pages will make it impossible for persons or organisations that are involved in the distribution of medicines in Nigeria to claim ignorance of the authenticity or otherwise of any regulated product they deal with.

The NAFDAC Green Pages was presented in three forms – book, CD ROMs and the Internet (www.nafdacgreenpages.org) – which makes it readily available to the public and amenable for updating in cases of registration of new products or the deregistering of old ones. The collaboration between NAFDAC and Zane in publishing the NAFDAC Green Pages illustrated some of the benefits derivable from a Public–Private Partnership. The beauty of the project was that it was successfully implemented at no financial cost to the Agency. Zane Designs

provided funding for the project, while we provided the necessary information from our registration database. Our usual practice of financing public enlightenment campaigns with our limited resources was thereby eliminated. NAFDAC was also paid 10 per cent from the sales of the publication.

The NAFDAC Green Pages was offered to the public on May 3, 2007, and it is currently available for purchase at all NAFDAC offices nationwide. Easier access to the information contained in the NAFDAC Green Pages will aid the public in making better-informed decisions about drug items before buying them.

Advocacy / Interaction with the Nigerian Government and Her Agencies

NAFDAC laws provide that the Agency interacts with other regulatory and government bodies such as the Nigerian Customs Service (NCS), Nigeria Ports Authority (NPA), Standards Organisation of Nigeria (SON), Federal Airport Authority of Nigeria (FAAN), Nigeria Police Force (NPF), Shipping Association of Nigeria (SAN) and the National Drug Law Enforcement Agency (NDLEA).

Advocacy with the Executive and Legislative Arms of the Nigerian Government

As part of our efforts to reposition NAFDAC for effective regulation of food and drugs in Nigeria, we saw the urgent need to return the Agency to the ports. NAFDAC had been excluded from all Nigerian ports for five years, from 1996–2001. I made a passionate plea to the then President for the reinstatement of NAFDAC at the ports, informing him that our absence at the ports contributed immensely to the prevalence of imported counterfeit medicines in Nigeria. He approved my request and NAFDAC was returned to the ports in October 2001. Furthermore, upon our recommendation, the Federal Government banned the importation of all NAFDAC regulated products through land borders and designated Calabar and Lagos (Apapa) seaports and Murtala Mohammed and Aminu Kano International Airports, as the only ports through which drugs and pharmaceutical raw materials could be imported. The Federal Government also directed the Nigeria Ports Authority (NPA), shipping lines and airlines to release all shipping and cargo manifests to our inspectors.

State Governors were not left out in the support for NAFDAC. The Governors of Anambra, Lagos and Kano States approved all the appeals we made for land allocation for the proposed Zonal Drug Distribution Centres (ZDDC). Our appeals for land for the construction of offices and laboratories also received favourable responses from the Governors of Cross River, Anambra, Gombe, Zamfara and Kano States. Many State Governments also provided

accommodation for our staff members in their respective states. In Kogi State, the traditional ruler of Ejule Local Government area donated a building for office accommodation. The traditional ruler of Okene in Kogi State also donated a piece of land for office accommodation.

We believe that the support of the State Commissioners of Health was crucial, since they are responsible for healthcare delivery at the state level. We invited them to meetings, the first of which was held on May 31, 2001. All the Health Commissioners from the 36 States of the Federation attended the meeting. We briefed them on the functions of NAFDAC and the problems of drug distribution in Nigeria and appealed to them to support our state offices in their enforcement activities. We also asked them to assist us in reactivating the defunct State Task Forces and set up monitoring units that would liaise with our state offices to enable us clamp down on counterfeiters in their states. We requested that they translate into their local languages our bi-monthly publications dealing with identifying characteristics of fake versus genuine products, so that people, especially those in rural areas, could spot the differences. We all agreed on the need for each State Governor to avail NAFDAC of the use of at least 30 minutes of airtime per week in their various State radio and television services and free newspaper space, at least once a week, to disseminate our messages to the citizens, especially to the grassroots. Cognizant of the fact that only the State Governors have the power to make this happen, I wrote to them for their help in this regard (Appendix 12).

The Health Committees of the Senate and the House of Representatives, (the upper and lower houses of Nigeria's National Assembly), also championed our cause. A Senator of the Federal Republic of Nigeria, by way of a private bill, sought to have NAFDAC's enabling laws amended for greater effectiveness. The bill went as far as the second reading.

The Nigerian Courts – The Judiciary

The slow pace of Nigeria's judicial system affected the performance of our statutory functions. Cases of violations lingered in courts. Accused persons abused the process by using injunctions and other court orders to stall our activities. Over the years, we spent a great deal of energy and scarce resources prosecuting hundreds of cases. Most of these cases turned out to be endless and frustrating. We also had problems with private lawyers whom we retained at different times to represent us in various courts. We believe that sometimes these lawyers, even after being paid all legal fees, connived with the accused persons. In one

such case, a highly placed lawyer and a Senior Advocate of Nigeria (SAN) settled a case out of court with our opponent, without informing the Agency of the terms of settlement and definitely without our consent.

As I conclude this book, some of the cases we initiated are still pending in the courts following delays and frustrations from incessant adjournments resulting from the death, transfer, suspension or retirement of the presiding judges. Cases transferred from one court to another; challenges to the jurisdictions of courts to hear cases; congestion in courts' cases lists; missing exhibits; inability of the police to produce accused persons; post-conviction counter appeals, as well as deaths and transfers of investigators, all add to the frustration. Encumbered by the daunting challenges we faced in the court process, we switched track, embracing the strategy of public enlightenment campaigns and advocacy.

In October 2007, in collaboration with the National Judicial Institute (NJI), we held a national conference in Abuja, on counterfeit pharmaceuticals and other substandard regulated products, for Nigerian judges. This conference was intended to become a regular feature in our regulatory calendar. It aims to continuously sensitise our judges on the scourge of counterfeit regulated products and to emphasise the strategic role of the judiciary in combating fake products in Nigeria. Worthy of mention was the exemplary decision by Honourable Justice Olayinka Faji, sitting at the Federal High Court Enugu, who sentenced Mr. Jacob Amadi to five years' imprisonment without option of fine. Justice Faji stated as follows, when the defence lawyer pleaded for leniency: "Even though he was a first offender it is necessary to make it clear that production of counterfeit medicines is a dangerous menace, an indirect form of genocide. It should not be tolerated." He also remarked that he was aware that section three of the Counterfeit Medicines and Unwholesome Processed Foods (Miscellaneous Provisions) Act, provides for the option of a fine for offenders, but that this would not apply in this case, as it would amount to allowing the accused person to use the proceeds of his dangerous business to pay for his crime.

Furthermore, we continued to collaborate with the Nigerian Bar Association (NBA), due to the strategic role they play in the administration of justice. We honoured several invitations from the NBA to address their members on the need for effective collaboration in the fight against counterfeit regulated products. For the most part, lawyers, on the prompting of their unscrupulous clients, instigate some of the frivolous and ill-motivated applications for injunctions to restrain us from pursuing counterfeiting cases. We have called and will keep calling on members of the NBA to bring their tremendous influence and clout to bear on

the legislature, to review some aspects of the NAFDAC laws, particularly in the area of sentencing of convicted counterfeiters. These criminals presently get minimal sentences for committing grievous offences.

The Nigeria Police Force (NPF)

On May 28, 2001, I paid a courtesy call on Mr Musiliu Smith, the then Inspector General of Police, to solicit his support for NAFDAC activities. Considering the fact that our staff members do not carry arms, we requested his assistance in posting police officers of proven integrity to work with us during our surveillance and enforcement activities. We also needed police assistance in ensuring speedy investigation of cases, protection for some of our key officers whose lives were endangered due to the nature of their job, and protection for our facilities and assets. Mr Smith provided us with adequate police security in my office and at home, as well as in our day-to-day operations such as raids on suspected business premises. Police protection was also extended to the Enforcement Director for obvious reasons. Successive Inspectors General of Police have continued to support our activities.

Nigerian Customs Service (NCS)

The Nigerian Customs Service (NCS) is one of the agencies responsible for the implementation and enforcement of the Government's trade and fiscal policies. One of their major functions is the control of all cargoes and goods entering, exiting or transiting through our national territory. As an important government agency, an effective and mutually cooperative relationship between NAFDAC and NCS would support our efforts to stop the importation of counterfeit medicines and other substandard regulated products through the ports.

The Ports Reform Decree 61 of 1999 (as amended) authorised only the following Agencies to operate at the various ports of entry: Nigerian Customs Service, Nigeria Ports Authority, Nigeria Immigration Services and the Ports Police. As a result of this reform, the NCS, at its discretion, might elect to invite NAFDAC for joint inspection of regulated products. Consequently, we were impaired in the execution of our statutory functions. This situation was resolved in October 2001 when NAFDAC was returned to the ports by a presidential fiat.

Most customs officials considered NAFDAC's presence at the ports as interference. As a consequence, there were conflicts between our staff members and the resident customs officers. To resolve these conflicts, a consultative meeting was organised for the management of both agencies. Furthermore, a list of our regulated products and specimen signatures of

our stamping and releasing officers were circulated to all the relevant customs bodies nationwide. In spite of these efforts, on several occasions, some NCS officers flagrantly disregarded our “Stop” and “Seizure” notices and released the offending products from the ports. In June 2001, at Apapa Port, our officer in charge of Port Inspection issued 30 “Stop” notices out of which only four were honoured. In July 2001, 15 Stop notices were issued and only one was honoured. A container load of 1,382 cartons of Nixoderm cream and Transversin cream imported from China, but fraudulently labelled as Made in Nigeria and Made in England respectively, were released by Customs in August 2001 in utter disregard of NAFDAC’s “Stop” notice on that container. As a result, I paid a courtesy call to the Comptroller-General of the NCS on September 5, 2001, to inform him of these dangerous and unhealthy events and to solicit the support of his organisation in our operations. Following the meeting, the Customs boss issued strong warnings to the officers, stating that any officer who released goods seized by NAFDAC would be summarily dismissed. I learnt that these warnings were issued regularly by the Comptroller-General, but were not taken seriously by customs officers. Some of our staff members also visited the ports several times, appealing to the Area Comptrollers at various terminals for their cooperation. These pleas were unsuccessful. The visits were subsequently followed up with letters to the NCS, to express our displeasure over their lack of cooperation (Appendices 13 and 14).

Another unresolved issue was the NCS’s periodic auctioning of overtime cargoes in all Nigerian ports. I believed that NAFDAC ought to have automatic representation in the Joint Committee for the disposal of overtime cargoes. This was necessary to avoid the auctioning of unwholesome, banned, expired and substandard regulated products and their release for sale to the public. For instance, a 40-foot container of expired pharmaceutical products was auctioned in Port Harcourt in July 2002. The Nigerian Customs Service also authorised the pre-release of bulk-regulated products, including fish, sugar, rice and vegetable oil, without prior notice to NAFDAC. Another issue of serious concern was the transfer of regulated products to bonded warehouses by customs officials. NAFDAC inspectors usually were not informed of such transfers, and sometimes such consignments ended up being diverted to unknown destinations.

However, the introduction of the Comptroller-General of Customs’ (CGC) Squad at the Lagos Ports brought about modest cooperation between NAFDAC and the NCS. The squad exhibited a very high sense of responsibility, referring cases of entries with fake stamps and forged signatures to NAFDAC. On several occasions, the Comptroller-General of Customs’

Squad referred regulated products released by resident customs officers without NAFDAC stamps back to NAFDAC. In appreciation of the Squad's activities, we wrote to the Comptroller-General of Customs commending members of the Squad for conducting their duties effectively (Appendix 15). I eventually learnt that this commendation letter led to the promotion of some members of the Squad.

The Standards Organisation of Nigeria (SON)

The Standards Organisation of Nigeria (SON) is the Federal Agency responsible for setting standards for all articles of trade. SON regulates and controls all items, except the seven categories of item regulated by NAFDAC. SON had a good working relationship with us, but occasionally, they encroached into our specific areas of responsibility. On one such occasion, SON released a consignment of sugar that was still undergoing quality tests in our laboratory. We promptly protested this action (Appendix 16). Such incursions are normally resolved through constant consultations between both agencies.

The National Drug Law Enforcement Agency (NDLEA)

The NDLEA is a complementary agency to NAFDAC. While we regulate the legal use of narcotics, the NDLEA controls its illicit use. The two bodies enjoy a positive working relationship. Shortly after becoming the head of NAFDAC, I paid a courtesy call to the then Chairman/Chief Executive Officer of the NDLEA, Alhaji Shaba Lafiaji, to solicit his support and to establish a collaborative partnership. He went ahead to deploy some of his staff members to assist us in our enforcement activities before the arrival of the police officers assigned to NAFDAC. However, we did not enjoy the same level of cooperation with his field officers. On one occasion, we had cause to protest to him over the interference of NDLEA officials with our activities at the Murtala Mohammed International Airport, Lagos.

The Nigeria Ports Authority (NPA)

The NPA is the custodian of the ports. As mentioned earlier, the Ports Reforms of 1996 banned NAFDAC from operating at the ports. The NPA, therefore, removed all NAFDAC owned structures within the ports' premises. When the ban was set aside in 2001, we held a consultative meeting with the management of the NPA, to discuss the modalities for our return to the ports. Following the meeting, we installed Portakabins as our offices in all the ports.

The NPA's refusal to release shipping manifests to NAFDAC in compliance with the Presidential directive remained a challenge. On several occasions, the NPA denied us access

to ship cargo manifests. I believe quite strongly that the influx of unregistered, fake and unwholesome regulated products into our country would be drastically reduced if correct and genuine shipping manifests were made available to NAFDAC before any vessel berths.

We continued to seek the cooperation of NPA, to ensure that finished pharmaceutical products, as well as raw materials, were not transferred to other ports or bonded terminals not designated for the importation of such products.

The Shipping Lines

The shipping lines are the major carriers of all products imported into Nigeria, including NAFDAC regulated products. Before the Port Reforms of 1996, a few shipping lines, such as Lansal, voluntarily cooperated with us by putting our “Hold” status on suspected unwholesome cargoes. After returning to the ports, no shipping line cooperated with us. As a result of this antagonism, we wrote to all shipping lines, decrying their flagrant violations of Nigeria’s laws, by facilitating the transportation of counterfeit medicines and unwholesome regulated products into the country. In January 2003, the Federal Government directed all shipping lines to furnish NAFDAC with all their cargo manifests. Unfortunately, the shipping lines, especially Maersk Line, failed to comply with the directive. We wrote to the Shipping Association of Nigeria protesting this utter disregard of a government directive. All shipping lines now comply with the directive. I consider this a noteworthy breakthrough.

Federal Airport Authority of Nigeria (FAAN)

The Ports Reforms of 1996 did not only affect NAFDAC operations at the land and sea borders, but also at the airports. Our offices at the airports in Lagos, Port Harcourt and Kano were shut down and our officials were denied access to the vital areas of the airports. The cargo sections became fast lanes for clearing imported NAFDAC regulated products.

When we returned to the ports, we appealed to the then Minister of Aviation, Dr Kema Chikwe, to issue to our officials, On-duty Cards (ODCs) and car stickers to grant them unrestricted access to all vital areas of the airports. She obliged and within days of issuance of the ODCs, some airlines, notably Ethiopian Airlines, were implicated in the importation of fake/unregistered drugs. We directed the airline to desist from aiding and abetting the transportation of fake and substandard products to Nigeria (Appendix 17). Since resuming operations at the airports, large consignments of fake and substandard regulated products have been impounded at the Murtala Mohammed International Airport in Lagos. In contrast, the Airport Facilitation Committee at the Aminu Kano International Airport imposed

restrictive orders against our officials, in spite of our ODCs and the ministerial directive. Our officers were therefore, unable to perform their statutory functions and had to rely on the personal goodwill of terminal managers to obtain vital information on the importation of NAFDAC regulated products.

International Advocacy

We had various forms of interaction with many international organisations such as the WHO, UNICEF, IAEA, DFID, PATHS and EOHSI. We enjoyed their active cooperation in the areas of information sharing, capacity building, donation of equipment and training. We also received support from Food and Drug Regulatory Agencies in the USA, South Africa, China, India, Singapore, Indonesia, Pakistan, Ghana and Belgium.

Consultative Meetings with Ambassadors of Countries Implicated in the Importation of Counterfeit Medicines

Although some European and Asian countries were implicated in the fake drug trade, mainly as transit ports, most of the counterfeit medicines imported into Nigeria come from India and China. In 2001, in concert with Nigeria's House of Representatives' Committee on Health, we held a consultative meeting with the High Commissioners/Ambassadors of India, China and some other countries we identified as sources of counterfeit medicines. The High Commissioners/Ambassadors and their representatives pledged their cooperation to curb the menace.

Indian Pharmaceutical Manufacturers and Importers in Nigeria (IPMIN)

This association of Indian drug manufacturers and importers was organised with the support of Mr Atish Sinh, the Indian High Commissioner to Nigeria, to assist us in our fight against counterfeit medicines. We held periodic meetings with members of this association. Their advice and tip-offs have been immensely helpful in accomplishing our objectives. The input of members of the association confirms that we have many genuine Indian companies operating in Nigeria.

India–Africa Health Summit

The Indian Government organised the India–Africa Health Summit in Mumbai, India from September 26 to 29, 2001, to create and strengthen the pharmaceutical trade between India and African countries. I was supposed to attend this meeting with the Health Minister, Prof. A.B.C. Nwosu, but we were scheduled to travel on different airlines. I arrived earlier and

waited for him, but for some reason, he could not make it to the meeting. I went to the opening ceremony with my assistant and the then Nigerian High Commissioner to India, Alhaji Ahmed. As the ministers were called to the high table, the High Commissioner asked me to go and represent Nigeria. I argued a little, considering the fact that the Minister did not ask me to represent him. The High Commissioner said that he had a right to ask me to represent the country and I reluctantly went to sit in the place of the Nigerian Minister of Health. I asked the High Commissioner what he wanted me to say, as I did not have the Minister's speech. He simply said: "Say whatever you want to say, don't worry, you have my permission."

As each of the African Ministers delivered their well-prepared papers, I contemplated silently what to say. Each minister spoke eloquently about their buoyant health budget, drug-purchasing system, the relationship of their country with India and other niceties. When it came to my turn, I thanked the Indian Government for inviting the Nigerian delegation. I also pointed out that Nigeria has had a long-standing cordial relationship with India in several areas. When I was in school, most of my lecturers were Indians and I found them to be hardworking and committed people. India has done very well in the Information and Communication Technology industry. India's pharmaceutical industry has also witnessed enviable growth in recent times. I then came up with my main point: "...the most important issue I want us to discuss in this meeting is that we in Nigeria are very unhappy that some Indian drug manufacturers are exporting counterfeit medicines into Nigeria and these have killed many people and destroyed the growth of local industries. It is more important than any other issue before us today, considering the fact that access to counterfeit medicines is worse than lack of access to drugs." I urged the conference to come up with a solution to the issue of fake medicines being exported from India to Nigeria and other developing countries. I added that Nigerian Government would not hesitate to ban the importation of drugs from India if the Conference and the Government of India took no official decision.

As I spoke, I watched the High Commissioner to see if he looked comfortable with my statements. His positive countenance greatly encouraged me. I therefore went on and on, pouring out my heart as this was a topic I felt very strongly about, and I explained that the pains Nigerians have gone through and continue to go through because of faked medication from India and other countries cannot be quantified. At some point, the conference organisers suggested that, in order not to derail the focus of the conference, I should have a meeting with the Commissioner of India's Food and Drug Administration, Mr. Ashwini Kumar, and

discuss how the Indian Government could help. At the end of the opening ceremony, I still did not feel comfortable, despite the High Commissioner's reassurances and the fact that most of the participants at the conference were eager to talk to me as if I was an extraordinary keynote address speaker. My uneasiness was because I felt that I had spoken too boldly on issues that I had no permission to speak on from Nigeria's Minister of Health. I arranged a breakfast meeting with Mr. Kumar in the hotel the following morning.

I spent the remaining part of the day and night thinking about the meeting and what to present to Mr. Kumar. By morning, it came to me like a flash. We could ask for permission to appoint an independent analyst in India who would recertify all drugs meant for export to Nigeria before they were shipped. I figured that if this eventually materialised, it would be at no cost to NAFDAC, as the cost would be borne by the exporter. During breakfast with Mr. Kumar, I told him that we had a solution that could be implemented immediately, and explained my plan for an independent analyst. He did not object to this suggestion. While I pondered over how to go about finding a suitable Indian analyst, Mr. Ramakant Gudal, the Chief Executive of FDA Mumbai, a man of impeccable integrity who was bold enough to send us the list of companies whose drugs failed quality tests in India, flashed through my mind. When I got in touch with Mr. Gudal to offer him the job, he told me that he had retired and therefore would be willing to accept the offer. His willingness to accept the job came to me as a pleasant surprise and we scheduled a meeting for later that day to discuss the conditions and terms. Mrs. Ukaegbu, my assistant, who was a NAFDAC Director, and the Nigerian High Commissioner to India were to join me in the meeting. Unfortunately, the High Commissioner left early for New Delhi and therefore could not attend the meeting. In the meeting, Mr. Gudal demonstrated strong eagerness to help. We agreed with him that the drug exporters would pay the fees for laboratory analysis plus a 20 per cent consultancy fee. All the paperwork relating to the agreement was prepared and signed at a later date. This was how we appointed our first foreign analyst.

In January 19, 2002, I visited India again with some staff members of NAFDAC to concretise our arrangement with the independent analyst and hold meetings with top government functionaries and other stakeholders. During that visit, we met with Mr. Kumar, Drug Controller of Maharashtra, the Indian Drug Manufacturer's Association and the pharmaceutical exporters. We reached the following agreements:

- (a) To adopt pre-shipment analysis of consignments meant for export to Nigeria by NAFDAC appointed independent analysts before export to Nigeria. We presented

Quality Control Services (QCS) owned by Mr Gudal as our independent analyst for pre-shipment tests;

- (b) To establish information exchanges between NAFDAC and India's FDA regarding the export of drugs;
- (c) NAFDAC to advise Nigerian importers to identify and associate only with genuine Indian manufacturers;
- (d) NAFDAC to stop registering or renewing registration of products for the merchant exporters who are the main fake drug exporters from India, because they do not have factories;
- (e) NAFDAC to register only genuine drugs from India which we can ascertain to be of acceptable quality;
- (f) NAFDAC to facilitate product registration once all registration conditions have been met;
- (g) Only WHO-certified companies, that have also satisfied NAFDAC's Good Manufacturing Practice (GMP) inspections, shall have their products registered with NAFDAC.

Every decision we reached was designed to protect the mutual interests of both countries, safeguard public health in Nigeria, restore public confidence in Made-in-India drugs and protect the businesses of genuine Indian manufacturers, exporters and their agents.

West African Drug Regulatory Authorities Network

As the Nigerian regulatory environment became stringent, drug counterfeiters became so uncomfortable that they started migrating to other West African countries, thereby worsening the problems of counterfeit medicines in those countries. Our success in Nigeria, therefore, was beginning to cast a dark shadow on our neighbours. In order to stem this tide, we needed strong and constant collaboration with drug regulators in the sub-region. I consequently decided to institute a regional collaboration by convening the first international conference of all West African Drug Regulators at Abuja, from March 15 to 17, 2006. During this meeting, a body known as the West African Drug Regulatory Authorities Network (WADRAN) was inaugurated. WADRAN provides a platform where heads of drug regulatory authorities in West Africa can share information and strategies and support one another in the fight against drug counterfeiting. It also provides an avenue for members to learn from

the NAFDAC experience and work in concert to ensure that the counterfeiters will not find a safe haven anywhere in the sub-region.

A communiqué was issued at the end of the conference, which contained concrete measures for combating counterfeiting of medicines within the sub-region. Some of the recommendations include:

- The need for effective collaboration of all West African Drug Regulators in order to succeed in combating counterfeit drugs in the sub-region.
- The need for information sharing on regulatory issues among member states.
- Every member country alerts other members of any detected counterfeit product in any of their ports or borders.
- Member countries adopt public enlightenment campaigns as a strategic weapon for fighting drug counterfeiting.
- Only registered products should be in circulation in member countries.
- The need for political support for drug regulatory authorities at the highest levels of government.

As a leading regulator in the fight against counterfeit medicines in the sub-region, I was elected the first Chairperson of WADRAN, with NAFDAC as the secretariat.

International Medical products Anti-Counterfeiting Taskforce (IMPACT)

At the WHO sponsored meeting on drug counterfeiting in Rome in February 2006, an International Medical Products Anti-Counterfeiting Taskforce (IMPACT) was proposed and supported by member countries. This Taskforce is to formulate and execute strategies for international collaboration. The establishment of IMPACT followed from our strong and sustained advocacy for the establishment of an International Convention against drug counterfeiting as is obtained for narcotics and psychotropic substances. Our advocacy started creating a new mindset among regulators, the industry, the world press, the pharmaceutical security institute, etc. We regard IMPACT as an interim measure which will eventually metamorphose into an international convention.

The preparatory meeting for IMPACT was held in February 2006 in Rome. Three countries, Nigeria, Ghana and Mali represented the West African Drug Regulatory

Authorities Network (WADRAN). The meeting had the theme: “Combating Counterfeit Drugs, Building Effective International Collaboration”, and a white paper “Declaration of Rome” was released. The meeting gave birth to the establishment of IMPACT and its Terms of Reference (TOR) include *inter alia*:

- To improve collaboration among governments, organizations, institutions, agencies and associations engaged in combating counterfeit medical products at the national, regional and/or international levels.
- To raise awareness among national and regional authorities and decision makers with a view to calling for effective legislative measures in order to combat counterfeit medical products.
- To establish effective mechanisms for exchange of information and to provide assistance on specific issues pertaining to combating counterfeit medical products.
- To encourage and facilitate coordination among different anti-counterfeiting initiatives.

The establishment of IMPACT was ratified at the 12th International Conference of Drug Regulatory Authorities (ICDRA) in Seoul, Republic of Korea in February, 2006. At this Conference, five working groups of IMPACT were constituted. They are the Legislative, Regulatory Infrastructure, Enforcement, Technology and Communication working groups.

The first general meeting of IMPACT was held in Bonn, Germany in November, 2006. This meeting elected a chairperson and vice chairpersons of IMPACT. I was elected a Vice – Chairperson.

Two of these working groups have held meetings and developed tools for review. The working group on Technology met in Prague, Czech Republic in March, 2007, and the Regulatory Implementation group met in Washington D.C, USA. Highlights of the meeting include: the review of the Regulatory Implementation mandate and work plan, exchange of information/rapid alert to combating counterfeit medical products, discussion on revisions for 1999 WHO COUNTERFEIT DRUG GUIDELINES, Regulatory focal points, data collection tools, Anti-counterfeit oriented Good Pharmacy Practices, Good Distribution Practices and Guidelines for the development of measures to combat counterfeit drugs.

Furthermore, there was the WHO start-up meeting on Technical Regulatory Package which took place from April 2-3, 2007 in Geneva, Switzerland. The aim of the meeting was to foster international collaboration among countries, encourage the development of minimum registration and regulatory standards among countries and subsequent signing of Memoranda of Understanding between these countries to facilitate the agreement reached. The meeting was to agree on the format of the WHO model Technical Regulatory Package and also to decide on the working procedure of field testing and further implementation of the model in selected African countries.

Trade Visit to Egypt with Nigerian Drug Manufacturers

To deepen the ongoing reforms in the pharmaceutical sector and introduce innovation, in September 2005, with the support of His Excellency, Ambassador Talaat, the Egyptian Ambassador to Nigeria, we went with a delegation of representatives of PMG–MAN, on a trade mission to Cairo in Egypt. The delegates explored possible areas of cooperation with their Egyptian counterparts. The manufacturers who participated in the trade mission returned home to put into practice the best practices they learnt from their experience in Egypt. They also developed useful business contacts with their Egyptian counterparts.

International Conferences and Meetings

In each country that I visited, I always tried to have meetings with as many stakeholders as possible, especially the regulators and drug exporters. In such meetings, I shared experiences with other regulators to sensitise them to the reality of drug counterfeiting, the inimical effect on humanity and the need for effective collaboration. During one such visit, the Nigerian Ambassador to Brazil, Mr. Kayode Garrick, facilitated the signing of a Memorandum of Understanding (MOU) between NAFDAC and the Brazilian Drug Regulatory Agency. I also benefited immensely from such meetings because they generally broaden my perspective on regulatory issues. At every meeting with drug exporters, I appealed to them to export only high-quality drugs to Nigeria and encouraged them to come to Nigeria and establish manufacturing outfits. For instance, my visit to Indonesia led to the establishment of at least two pharmaceutical, one cosmetics and two food factories in Nigeria.

The 10th International Conference of Drug Regulatory Authorities (ICDRA) meeting, which took place in Hong Kong in June, 2002, was my maiden opportunity to meet one-on-one with most heads of drug regulatory authorities across the globe. The meeting was convened to discuss herbal medicine regulation. After presenting a paper on *How Regulation of Herbal*

Medicines was Established in Nigeria, I used the opportunity to highlight the issue of counterfeit drugs as a global problem. I categorically communicated our total abhorrence of “For Export Only” labelled drugs moving in international commerce. I also started a campaign that ICDRA should advocate for the establishment of an international convention on counterfeit medicines, just as we have for narcotics and psychotropic substances, which will lead to a harmonised regulation of pharmaceutical products moving in international commerce. This proposal attracted tremendous support from participants. Since then, we have used every opportunity to continue with this advocacy in every forum and it is catching on.

At the first Global Forum on Pharmaceutical Anti-Counterfeiting held in Geneva in September, 2002, under the auspices of Reconnaissance International, I presented an address entitled *Understanding the Problem: The African Perspective with Special Emphasis on Nigeria*. That provided me with a platform to project our concerns on the counterfeiting of pharmaceuticals and I renewed my call for an international convention for counterfeit medicines. Reporting on the event in Tribune De Geneve, on September 25, 2002, Fabrice Sreithaupt stated in part: “The risks due to counterfeit medicines are more widespread than those of AIDS and MALARIA put together. The energetic Dr Dora Nkem Akunyili could not put it more clearly yesterday night during the press conference organised at the first worldwide forum on the fight against counterfeit drugs.” I strongly felt the need to carry this campaign to every international conference I attended, to raise the standard of global consciousness, until it was implemented. This position was reiterated in many of my presentations, a few examples of which are:

- *Counterfeiting as a Global Problem* at the British Pharmaceutical Conference (BPC), UK, from September 15–17, 2003;
- *Fake/Counterfeit Drug Eradication in Nigeria* at the International Regulators Seminar Series, organised by the USFDA, USA, on November 24, 2003;
- *The Regulation of Herbal Medicines in Nigeria* on February 18, 2004, at the 11th ICDRA meeting in Spain, where the WHO actively supported the proposal for establishing the convention and it was also included in the conference recommendations.
- At the conference on “Strategies for Enhancing Access to Medicines” (SEAM), held from June 20–22, 2005, in Accra, Ghana, I presented a paper entitled, *Is the Time Ripe for an International Anti-Counterfeiting Commission?* After the conference, the SEAM group urged the World Health Assembly (WHA), to adopt the recommendations of the 11th ICDRA meeting on counterfeiting of pharmaceuticals.

- At the Harvard Business School, Boston, USA, in February 2008, I presented a paper entitled: *Governance in Africa: My Leadership Experience in Fighting Corruption Related to Drug Counterfeiting in Nigeria*.

Many other speeches on drug counterfeiting were delivered at various conferences both in Nigeria and abroad. The last in this series delivered before I left NAFDAC was: *Combating Counterfeit Medicines: The Nigerian Experience*, at the 68th FIP conference at Basel, Switzerland, August 29–September 4, 2008.

At the international level, our focus was not limited to counterfeit pharmaceuticals alone. I also attended and presented papers relating to other areas at various international conferences. Some of them are:

- *The Codex Alimentarius Commission* held in Geneva, Switzerland from July 2–7, 2001, where I was head of the Nigerian delegation to the meeting. I spearheaded the defence of the position of the delegates from developing countries on the retention of 0.5mg/kg (maximum level) of lead in cocoa, as against the proposed, more stringent lead content of 0.1mg/kg favoured by the developed countries, because there were no proven health implications even at the 0.5mg/kg level. I posited that the proposed action would adversely affect the economy of the West African Region and advocated for a period to enable the best practices that would reduce the lead content in cocoa. With the help of other African countries, we were able to convince the meeting not to adopt the new level of lead content in cocoa and this saved the Nigerian cocoa market because we knew that it was going to be difficult for us in the developing countries to achieve the new level too soon.
- The Food for Africa International Working Meeting held in Yaoundé, Cameroon on May 5, 2003 with the theme: *Workings of NAFDAC with Special Emphasis on Quality Systems for Food*;
- *Reinventing Business in Africa: From Entrepreneurship to Corporation; Challenges of Food and Drug Regulation – My NAFDAC Experience*, at the Wharton African Business Forum, Wharton Business School, USA, on November 15, 2003.
- *Women Leaders in Emerging Democracies – My Experience as Head of Food and Drug Regulation in Nigeria*, at the University of Pennsylvania, USA, on November 17, 2003.
- *The Role of NAFDAC in Promoting Trade Relations in Food Products Between Nigeria and South Africa*, in South Africa, on August 3, 2005.

- *Nigerian Standards for Food and Drugs*, in Munich, Germany, on October 26, 2006.
- *Current Food Drugs and Cosmetics Regulatory Climate in Nigeria: Recent History, Current Successes and Challenge*, in Houston, Texas, USA, on September 15, 2007.
- *Enforcement of Intellectual Property Rights (IPR) in Nigeria: The Role of NAFDAC*, at the Global Intellectual Property Event in Washington, DC, USA, on April 15, 2008.

CHAPTER 11

STRATEGY IV: WALKING THE ROUGH ROAD OF DISCIPLINE

Violations and Sanctions

In 2002, Chief Afe Babalola, a Senior Advocate of Nigeria (SAN) stated: “Until recently, all sorts of food, drugs and other products were imported into the country from all parts of the world, with little or no control and without due payment of the customs’ duties. Serious monitoring in the real sense of it was virtually non-existent. However, in the past few months, things have changed so dramatically that people wonder whether NAFDAC is a new Agency set up by a new law, or just President Obasanjo’s anti-corruption crusade at work.”⁵⁴ The sanitation of the food and drugs environment in Nigeria, which the public was beginning to see, was brought about by the enforcement of rules and application of sanctions to defaulting individuals and businesses. The two main operational laws we employ in applying sanctions against offenders are the Counterfeit and Fake Drugs and Unwholesome Processed Foods Decree 25 of 1999 and the Drugs and Related Products (Registration) Decree 19, 1993 (as amended). Recognising the gross inadequacies of our time-consuming judicial processes and precious resources wasted in prosecuting offenders, we developed guidelines, which are permitted by the existing laws. These new guidelines have stiffer penalties and have been quite effective. However, individuals and businesses who committed very serious violations were still prosecuted. We were particularly careful to ensure that sanctions are applied equitably, because generally, people are more amenable when there is equity in application of penalties. The following are some of the sanctions we employed:

“Holds”

This is a limited type of seizure where the regulated products cannot be removed, distributed or sold by the owner until decisions are made by the Agency. For instance, an unregistered food or cosmetic is kept on hold until tests are completed to assure safety and quality before it is released. Depending on the outcome of the test, the products are either destroyed or released on payment of the stipulated fine by the importer. Production lines and sometimes entire manufacturing units may be placed on hold where the GMP standards are found to be

grossly inadequate, or where there are serious consumer complaints, until all the unacceptable issues are addressed. Imposition of a fine depends on the magnitude of the offence – details are spelt out in our Standard Operating Procedures (SOPs).

Seizure of Products

During the inspection of imported consignments, routine monitoring and surveillance inspections, identified fake, counterfeit and substandard products are seized and transferred either to our warehouses or to bonded warehouses.

Letters of Warning and/or Compliance Directives

For minor offences, we issue letters of warning and/or compliance directives to the offenders. In the case of a factory or warehouse where there are minor GMP lapses, compliance directives are issued. Failure to comply with the directive will result in closure of the affected product line or total factory closure or sealing up of the warehouse.

Administrative Fines

The new NAFDAC administration adopted graduated fines to deal with offences that are not serious enough to warrant prosecution. Such offences include relocation of business premises without notice to the Agency, labelling lapses, or the manufacture, importation or sale of unregistered but genuine and wholesome non-pharmaceutical regulated products.

Sealing-Off Factories or Warehouses

If the unwholesome product poses a serious threat to public health, or there is proven intent to cheat or deceive, or where the GMP is so poor that it can affect the product, the factory or warehouse is sealed up.

Forfeitures

Where establishments or individuals are found in possession of identified fake, counterfeit, substandard or unwholesome products, such products are forfeited to the Agency for destruction. The owner of the products usually does the forfeiture in writing.

Prosecution

NAFDAC prosecutes all recalcitrant violators of regulated product rules and regulations and counterfeiters of food and drugs.

Destruction

All seized and forfeited products are destroyed by NAFDAC, in conjunction with relevant agencies, such as the State Environmental Protection Board and Customs where applicable. The offending persons and companies bear the cost of the destruction.

Deregistration of Products

A product may lose its registration status if it is banned, abused or misused or new serious adverse effects are discovered. It may also lose it if it is found to have obtained registration status through fraudulent means like falsified documents, or if there are significant changes in the conditions under which the product was granted initial marketing authorisation, or refusal to allow NAFDAC officials to inspect production facilities. The deregistration is clearly communicated to the public, with reasons, through alert notices.

Blacklisting

Companies, both local and foreign, identified as sources of fake or substandard drugs are blacklisted from exporting regulated products to the Nigerian market. We publish a list of such blacklisted companies, and circulate it, not only in Nigeria, but also to WADRAN member countries. In 2002, we alerted the public to five Chinese and 14 Indian companies that persistently exported counterfeit medicines to Nigeria. The blacklisted companies were banned from exporting drugs to Nigeria, and Nigerian importers were discouraged from dealing with them. In 2005, 11 new Indian companies and one Pakistani company confirmed as fake drug producers were banned from exporting drugs to Nigeria. In 2008, we blacklisted 12 pharmaceutical companies comprising seven Indian and five Nigerian companies.

The 2008 Blacklisting

The chain of events that led to the blacklisting of 12 companies brings to the fore the effectiveness of our independent analyst in India and clearly reveals how the advances of computer technology can be turned to criminal use. The blacklisting was because of investigations into activities of these Indian companies and their Nigerian Agents from July 2006 to September 2008. The banned Indian companies were made up of drug exporters and manufacturers, while the banned products were fake and bore fraudulently affixed

NAFDAC registration numbers belonging to other registered products. The banned companies fell into the following categories:

1. Companies involved in the production, importation and distribution of substandard, fake and counterfeit products.
2. Companies involved in the forgery of NAFDAC registration certificates and other documents.
3. Companies involved in hacking into the NAFDAC Registration Database (NARPAD) to manipulate the data. Such companies were able to input names and NAFDAC numbers for their unregistered products and change manufacturers' names in our database.

Table 2: List of Companies Blacklisted in 2002

	NAME OF COMPANY	COUNTRY
1	Sinochem, Ningbo Import & Corp.	China
2	Yantai Foreign Economic & Technical Trade Corp.	China
3	Honest Trading Co. Ltd.	China
4	Hubei Provincial Medicines & Health Products Imports & Exports Company	China
5	Qingdao Yili Pharmaceutical Company Ltd.	China
6	Pharmadeal Pvt. Ltd.	India
7	Wellcure Drugs and Pharmaceutical Ltd.	India
8	Comet Pharmaceuticals Pvt. Ltd.	India
9	Coral Laboratories Ltd.	India
10	Unison Drugs Pvt Ltd.	India
11	Novus Pharmaceuticals Ltd.	India
12	Sangola Pharma, Owned by Raj SHAH	India
13	Wellbert Pharmaceutical (Bombay) Pvt. Ltd.	India
14	Medico Remedies Pvt. Ltd. (manufacturers of Pharmaceutical formulations)	India
15	Milan Medical Stores	India
16	Santacruz Medical Stores	India

Table 2 contd.

	NAME OF COMPANY	COUNTRY
17	Uma Medical Agency (Pharma Distributor)	India
18	Sangula Enterprises (Manufacturers of Surgical Dressing)	India
19	Rose Pharmacy	India

Table 3: List of Companies Blacklisted in 2005

	NAME OF COMPANY	COUNTRY
1	Kamala Overseas Bombay	India
2	Vardhman Export A-188 TTC	India
3	Unibios Lab Limited	India
4	Shreechem Pharmaceuticals Pvt. Ltd.	India
5	Merit Organics Ltd.	India
6	Milan Laboratories	India
7	Pliva Pakistan (Pvt.) Limited	Pakistan
8	Mission Pharmaceutical Ltd.	India
9	Henkish Chemical Pvt. Limited	India
10	Intermed 4GK	India
11	Wardex Pharm Pvt. Limited	India
12	Dew Healthcare Pvt. Limited	India

- * Serious cases like importation of expired, fake or counterfeit drugs, banned products and unwholesome food are referred to the Enforcement Directorate for further investigation and prosecution without the option of a fine. Parallel importation of registered drugs or importation of clones of registered drugs and drug products is also prosecuted with no option of a fine. Such cases are also referred to our Enforcement Directorate and handled by a special team comprising NAFDAC officials and law enforcement agents.

Table 4: List of Companies Blacklisted, and their Violations, in 2008

S/N	COMPANIES	VIOLATION
1	Medicare Pharma Ltd., Lagos	The MD, Mr Maduabuchi, was responsible for fraudulently affixing NAFDAC registration numbers to drug products that did not go through the registration process. He affixed fake NAFDAC reg. nos. to 8 products using Baader Schultz, Empree, Ciron & Lincoln as manufacturers. Mr Maduabuchi collaborated with M/S Janak Associate, Unity Pharma India and Baader Schultz India to export counterfeit medicines to Nigeria with forged documents. Unity Pharma, India & M/S Janak Associates provided evidence to show that Mr Maduabuchi provided them with the forged documents and NAFDAC nos. which they used for the manufacture of the products.
2	O'Neil Pharma & Healthcare Ltd., Lagos	Mr. Maduabuchi is also the owner of O'Neil Pharma & Healthcare Ltd. Lincoln Pharm also implicated O'Neil in the supply of forged documents and NAFDAC nos.
3	Nexus Pharma Ltd., Lagos	Brought in products in the name of Oni Pharm without Oni's knowledge using M/S Janak & Association.
4	M/S Sanchuks Global Association	Involved in the importation of counterfeit <i>Tramal</i> .
5	M/S Tmoor Int'l Co. Nig. Ltd., Kano, Nigeria	Involved in the importation of counterfeit <i>Tramal</i> through Usan & Selvok.
6	Baader Schultz Laboratory Daman, India	Collaborated with M/S Janak Associates and Mr. Maduabuchi of Medicare to export drugs to Nigeria using forged documents.

Table 4 Contd.

S/N	COMPANIES	VIOLATION
7	M/S Janak & Associates, India.	M/S Janak Associates collaborated with Mr. Maduabuchi of Medicare and O'Neil to use forged documents to export drugs to Nigeria. The forged documents enabled Baader Schultz to manufacture drugs for Medicare, O'Neil and others.
8	M/S Phakt Overseas India	The company submitted that they used a loan licence to manufacture using Asoj, Gelnova and Swiss Parenteral. We confirmed that they used forged documents to export drugs into Nigeria in collaboration with Kolsh Nig. Limited, Ogun State. They changed manufacturing source from Cambay to Asoj because QCS would not issue CRIA, since M/S Phakt could not obtain COPP from Cambay.
9	M/S Unity Pharma Pvt. Ltd., Mumbai, India	They exported drugs to Nigeria with forged documents.
10	M/S USAN Pharma Centicals Ltd., Mumbai, India	Exporter of counterfeit <i>Tramal</i> . The FDA Maharashtra also confirmed the seizure of huge stocks of counterfeit <i>Tramal</i> from USAN.
11	M/S SELVOK Pharm Co. Ltd., India	USAN& Selvok is involved in the production of counterfeit <i>Tramal</i> and <i>Vega-100</i> (Sildenafil).
12	M/S Promo Lifescience, Mumbai, India	Investigation by QCS showed that they had been involved in exportation of counterfeit <i>Vega-100</i> tab and other counterfeit drugs to one Adams Isa Mohammed of Niger Republic. This was revealed during investigation of SELVOK and USAN.

Sanctions

From April 2001 to September 2008, the following Directorates recorded the following number of violations and corresponding sanctions:

Directorate of Ports Inspection– 11,559

Establishment Inspection– 24,444

Registration & Regulatory Affairs– 582

Narcotics & Controlled Substances – 69

Enforcement recorded–260

Violations are classified either as major or minor. Major violations attract immediate sanctions such as seizure of the offending products for destruction, outright closure of the premises, sealing off of affected product lines, placing affected products on hold pending laboratory test results, product recalls, a public apology by the violator and the arrest and detention of violators for possible prosecution. Minor violations attract issuance of compliance directives, which must be effected within a stipulated time, issuance of a letter of warning, termination of unauthorised product advertisements, the imposition of administrative fines and a letter of undertaking by the violator pledging never to repeat the offence.

Violations include importation, production, storage, distribution and sale of:

- * Fake products
- * Unregistered regulated products
- * Expired products
- * Substandard products
- * Banned products
- * Products found to have degenerated due to poor storage and handling
- * Products with the wrong packaging
- * Expired, substandard or banned raw materials
- * Controlled substances such as narcotics, weapon precursors and ozone depleting substances (ODS) without permits
- * Chemicals without permits
- * Products in unregistered pack sizes

- * Products with unapproved labels
- * Products with a fake NAFDAC number
- * Products in excess of quantities specified in the permits
- * Products with fake NAFDAC permits for test samples
- * Products with falsified import documents
- * Products without certification from NAFDAC independent analysts
- * Drug products without pre-shipment information to NAFDAC
- * Drug products without a NAFDAC bank clearance permit

Other violations include:

- Alteration of the contents of permit
- Falsification of documents
- Late renewal of registration licences
- Parallel importation
- Unauthorised advertisement of regulated products
- Storage of chemicals in unauthorised premises such as residential buildings
- Storage of chemicals under improper conditions
- Handling of chemicals without the necessary safety facilities and gadgets
- Lack of proper documentation on the disposal of controlled substances and chemicals
- Submission of misleading or inaccurate disposal records
- Marketing of chemicals without a Listing Certificate
- Denying regulatory officers access
- Non-implementation of compliance directives
- Unapproved extension of product lines
- Relocation of production facility without notifying NAFDAC
- Changing of key personnel without notifying NAFDAC

- Reformulation of product without authorisation from NAFDAC
- Producing under poor GMP standards, for example:
 - Inadequate personnel
 - Poor sanitary conditions
 - Lack of adequate equipment and facilities
 - Poor documentation
 - Poor storage facilities
 - Arbitrary fixing of shelf life without regard to acceptable scientific procedures.

The sanctions applied for these violations depended on the severity of the cases. For example:

- * All expired or unwholesome regulated products are destroyed at the importers' expense and we bear the destruction cost when the importer absconds or is not available.
- * In the past, unregistered drug products were released conditionally on bond and placed on hold, while the importer processed the registration of the products. Fines were issued against the importer for violating relevant laws. We did this at the beginning of our reform programme to encourage compliance. We soon discovered that it was subject to abuse and it has since been discontinued. Presently, all unregistered drug products intercepted at the ports are seized and destroyed.
- * Unregistered but wholesome food products attract administrative fines. When products of a perishable nature are confirmed to meet standards and the assessed fines duly paid, they are released to the importer with a letter of warning issued to him or her. The importer is made to submit a written undertaking pledging not to import unregistered products again. As a classic example, a popular brand of tinned fish, which had been in circulation in our markets for decades, but had never been tested, certified, or registered by NAFDAC, was intercepted at the port. The cargo was placed on hold, tested and certified to be wholesome. The importer was fined and issued with a letter of warning. He submitted an undertaking pledging never to import unregistered products. Hypothetically, if the result of the laboratory analysis had been unsatisfactory, the owner would have had to forfeit the entire consignment for destruction at his expense.
- * Parallel importation of non-drug products attract fines of ₦5,000,000 (US\$43,478) for a 40ft container, ₦3,000,000 (US\$26,086) for a 20ft container and ₦2,000,000 (US\$

17,391) for half of a 20ft container or less. Parallel importation occurs when a genuine product is imported from a manufacturer or from any other source by a party other than the holder of the marketing authorisation for that product.

- * If there is no prior pre-shipment information for the importation of a genuine pharmaceutical product, a fine of ₦1,000,000 (US\$8,695) is levied against the importer; forgery of NAFDAC release stamps attracts a fine of ₦500,000 (US\$4,347); false declaration of documents, concealments and document alteration attracts a fine of ₦500,000 (US\$4,347); labelling defects attract a fine of ₦50,000 (US\$434). These falsifications, false declarations or concealment by genuine importers are usually done to avoid payment of duties and other official fees or to avoid delay.
- * Serious cases like importation of expired, fake or counterfeit drugs, banned products and unwholesome food are referred to the Enforcement Directorate for further investigation and prosecution without the option of a fine. Parallel importation of registered drugs or importation of clones of registered drugs and drug products is also prosecuted with no option of a fine. Such cases are also referred to our Enforcement Directorate and handled by a special team comprising NAFDAC officials and law enforcement agents.

CHAPTER 12

SPECIAL CASES

NAFDAC received reports of frequent violations of our laws from different parts of the country. After investigations that usually follow such reports, the Enforcement Directorate and the Legal Division would work together to prosecute the offenders where applicable. In most cases, fines are imposed, but in the case of fake medicines, they are destroyed. We handled violations impartially, irrespective of persons and/or organisations involved in the cases. So far, we have secured 49 convictions. This chapter highlights some of the important violations and how they were handled.

Drug Cases

The Use of Counterfeit Medicines for Open Heart Surgery at the University of Nigeria Teaching Hospital (UNTH), Enugu

We woke up on the morning of July 19, 2003, to read a frightening incident reported in the Nigerian Guardian newspaper entitled How Counterfeit Medicines Undid What Cardiologists Did. The story was that two out of thirteen children who were beneficiaries of surgery sponsored by a charity organisation, the Kanu Nwankwo Heart Foundation, founded by the Nigerian international soccer star, Kanu Nwankwo, died as a result of fake cardiac stimulants administered on them during the procedures.

Alarmed by this report, we launched an immediate investigation into the claims. The nature of this incident was such that I personally took charge of the investigations and led a team of NAFDAC officers to UNTH, Enugu on July 21, 2003. We interviewed the people involved in the case, particularly key hospital personnel and participants in the operations. We inspected the hospital's pharmacy and the drug stores and examined their drug purchase records. We also visited some pharmacies close to the hospital and the open drug markets where most of the drugs used for the surgeries were purchased.

Investigations revealed that the brand of Adrenaline initially supplied for the procedures was withdrawn because the surgeons found it ineffective. It was then replaced with other brands. Four different brands and six different batches of Adrenaline were supplied and

were used during the surgical procedures. We found that only two of the hospital's drug suppliers were duly registered and operated under the supervision of pharmacists. All the other suppliers were unregistered and non-professionals but their companies fraudulently bore the name Pharmacy.

Physical examination of six batches of Adrenaline drawn from the hospital's store revealed that one batch had no date of manufacture, another had no name and manufacturer's address and the third had turned light brown from its original colourless nature. None of these three batches should ever have been allowed into the hospital in the first place. Laboratory analysis of other drugs such as Dextrose injection, Dextrose saline infusion, Normal saline infusion and Ringer's lactate solution drawn from the hospital's store showed that one of the three batches of 50 per cent Dextrose intravenous injection failed Pyrogen tests, while one of the three batches of the 10 per cent Dextrose intravenous injection failed sterility tests. (A Pyrogen test is designed to limit to an acceptable level the risk of a sudden temperature rise in a patient as a reaction to a particular injection.) In addition, the Isoplasma infusion used for the operations contained far less calcium, and had a higher pH value, than the specifications on the pack. By implication, the medicines were unfit for human use and yet they were injected into the patients before, during and after such sensitive operations. Furthermore, there were no medical records indicating the particular batches of infusions or the particular batches of Adrenaline used on each patient. Perhaps some patients survived because they received infusions and/or Adrenaline from the good batches. All the 20 drug-selling outlets that were directly or indirectly involved in supplying these drugs were shut down to allow for proper investigations. The people who supplied the drugs to the hospital were arrested and made to reveal the places where they bought the fake medicines. It was in this process that we found that the three batches of fake Adrenaline were bought from an open market at Onitsha. When we apprehended the supposed seller of the drug in Onitsha market, he denied ever selling those drugs to anybody. We could not pursue this case further at the Onitsha end because the receipt given to the pharmacist by the Onitsha trader had neither name nor address. It was the word of the pharmacist against the word of the trader. The muscle relaxant (suxamethonium) used for the surgeries was found to be of low potency. We wrote a detailed report on these investigations and submitted it to the Minister of Health for necessary action.

Contaminated My Pikin Baby Teething Mixture

On November 19, 2008, we received a telephone report on the death of eight children at the Ahmadu Bello University Teaching Hospital (ABUTH), Zaria. We promptly dispatched

a team of NAFDAC staff from Kaduna to the Hospital on the same day, to investigate the report.

The paediatrician, the pharmacist, a resident doctor, a principal nursing officer and the parents of the children were all interviewed. Our investigations revealed that 11 children were referred to the hospital from Kaduna town. All the children had diarrhoea, vomiting, fever and convulsions and were unable to pass urine for days. By November 20, 2008, eight out of the 11 children had died, while three were undergoing dialysis. Further investigations revealed that all the children had taken My Pikin Baby Teething Mixture, a syrup containing Paracetamol BP 120mg and Diphenhydramine HCl BP 6.25mg, produced by Barewa Pharmaceuticals in Lagos. Three bottles of three batches of the mixture were retrieved from the Head of the Paediatrics Department, ABUTH.

It was during this investigation in Zaria that we learnt of a similar incident at University College Hospital (UCH), Ibadan and Lagos University Teaching Hospital (LUTH), Lagos. We immediately dispatched our officers to both hospitals to investigate the reports. Our team visited UCH on November 24, 2008 and held discussions with the Chief Medical Director (CMD) and other key management staff of the hospital. The NAFDAC team was informed that between October 30, 2008 and November 24, 2008, seven paediatric patients aged 1–3 years were referred to UCH, Ibadan from some hospitals in Lagos. Two out of the seven toddlers died whilst in UCH, Ibadan, while the others were taken back to Lagos by their parents, against medical advice.

At LUTH, our investigations revealed that 20 children were hospitalised, out of which 15 died. A 14-month-old baby was also reported to have died on November 2, 2008. By December 1, 2008, three more children had died in ABUTH. The official death toll due to the contaminated My Pikin mixture reported by the media across the country was over 70 children. In all the recorded cases at ABUTH, UCH and LUTH, the drug used in common by all the patients was My Pikin. Unfortunately, we could not obtain samples of the drug from UCH and LUTH.

The samples retrieved at ABUTH, Zaria and those collected from many retail outlets in Kaduna, Ibadan and Lagos were sent to NAFDAC laboratories for analysis. Since we had got reports from the hospitals that babies were developing kidney failure and some were dying after ingesting the syrup, we felt it was necessary to alert the public so that people would stop selling and using the product while we awaited the outcome of the laboratory results. An alert notice was put on radio and television, asking the public to stop the use of

My Pikin and report any suspected case to NAFDAC for immediate action. All medicine outlets, stores, clinics and hospitals were directed to urgently withdraw from circulation all batches of My Pikin and surrender them to the nearest NAFDAC office. They were also told that failure to do so would attract severe sanctions.

After midnight on November 24, 2008, we received the laboratory results showing that the mixture contained Diethylene glycol, an antifreeze that causes death by kidney failure. As at November 25, only one batch manufactured on August 10, 2008 contained Diethylene glycol. NAFDAC's last routine inspection of the manufacturer's plant was on August 8, 2008, which was two days before the manufacture of the contaminated product. The routine inspection gave a clean report to Barewa Pharmaceuticals because as of the date of the inspection, the offensive Diethylene glycol had not been purchased. On confirmation that My Pikin contained this toxic chemical, NAFDAC closed down Barewa Pharmaceuticals and wrote a letter requesting the company to recall all batches of My Pikin from their distributors and inform NAFDAC when this had been done. They promptly complied and sent us copies of the recall letters sent to all their distributors.

NAFDAC officers nationwide were instructed to remove all batches of the product from circulation. We also sent officers to the Local Government Areas and villages to remove the teething mixture in rural areas. While removing all remnants of My Pikin syrup from retail outlets in the rural communities, NAFDAC field officers involved were also instructed to disseminate information on the "killer syrup" to community leaders, schools, churches and mosques. We also appealed to religious leaders to help in disseminating the information to their congregations during worship. Appeals were made to members of the national legislature for help in spreading information on the effects of this product in their various constituencies. We also wrote to all State Governors requesting that they help us translate the information into their local languages.

The retrieval exercise carried out across the country was hitch-free except in Port Harcourt, Rivers State, where a pharmacist, Mr. T. Makinde of Tomak Pharmacy, was arrested and had his pharmacy sealed off due to uncooperative activities. Mr Makinde had travelled to Aba to retrieve all My Pikin teething mixture he had supplied to his customers and hid them. When our officers in Aba got the information, they relayed it to our officers in Port Harcourt, from where officers immediately accosted him and demanded that he surrender the drugs to NAFDAC. His refusal to surrender the drugs in his possession led to his arrest and detention and several other unregistered drugs were subsequently recovered from his pharmacy. He

was later released on a bail bond of ₦500,000 (US\$ 4,347). The largest quantities of My Pikin were recovered in Kaduna and Lagos States respectively and 5,334 bottles were withdrawn across the country.

Detailed laboratory analysis conducted on the various samples mopped up showed that the contaminated My Pikin Syrup contained Diethylene glycol in the range of 6.75 per cent to 91.0 per cent. The mixtures containing over 90 per cent Diethylene glycol suggest that the supposed Propylene glycol purchased by Barewa Pharmaceuticals could have been 100 per cent Diethylene glycol. The mixtures containing less than 90 per cent of the toxic chemical could have been diluted with the correct Propylene glycol in the production line. We conducted tests on other brands of Paracetamol syrup from all over the country to ensure that they were not contaminated with Diethylene glycol. NAFDAC laboratory staff literally worked around the clock to ensure speedy completion of the analysis. We found all other brands of Paracetamol syrup to be satisfactory. Thereafter we ordered 100 vials of Fomepizole injection, the antidote to Diethylene glycol, from London. As soon as the antidote was received, it was distributed to various teaching hospitals around the country.

We commenced investigations to find out the original source of the toxic Diethylene glycol. We also needed to find out who smuggled the antifreeze into the country, since we had never given any permit for its importation. We found that Barewa Pharmaceuticals bought what was supposed to be Propylene glycol, but which must have been Diethylene glycol, from Tranxell Limited, a Lagos based company. Barewa Pharmaceuticals bought this chemical in a plastic container other than the final container usually accompanied by a certificate of analysis, as required by Good Manufacturing Practice. The container had no label and no seal. They also failed to adhere to their usual SOP of testing the raw material before production. It appeared that Barewa Pharmaceuticals ran out of Propylene glycol, the raw material, and were in a hurry to continue production. Thus, Barewa Pharmaceuticals bought Diethylene glycol, or Diethylene glycol mixed with Propylene glycol. Whichever is the case, there was none left in the container to enable NAFDAC investigators ascertain whether the Diethylene glycol contained Propylene glycol.

The Managing Director of Tranxell, Mr Ikem Omalu, who supplied the chemical to Barewa, was arrested and his shop was closed down. Tranxell was also found to have supplied Propylene glycol to Gauze Pharmaceuticals Limited based in Awka, Anambra State and Sagar Overseas, a textile company based in Lagos. Gauze Pharmaceuticals was also closed down. Sagar Overseas uses the chemical as a resin in textile operations. Further investigations

revealed that Sagar was going out of business so they sold the Propylene glycol they purchased from Tranxell to Juhel Pharmaceuticals, Enugu. Consequently, the liquid line of Juhel Pharmaceuticals was sealed off and samples of their finished liquid preparations along with relevant raw materials were collected for laboratory analysis. In addition, we also closed down all shops connected to selling or buying Propylene glycol from Tranxell.

Gauze and Juhel pharmaceutical companies bought their Propylene glycol in properly sealed original containers with a certificate of analysis, but we needed (in line with our SOP) to properly investigate all Propylene glycols bought directly or indirectly from Tranxell Limited. Laboratory analysis of syrups from Gauze and Juhel pharmaceutical companies were found to be satisfactory, and the two companies were allowed to continue production.

On interrogation, Mr Ikem Omalu of Tranxell explained that he bought the chemical from a shop owned by Mr Emeka Onwalia, who in turn claimed that he bought it from Kenneth Azogba. Mr Azogba claimed that he bought the chemical from Mr Chinwendu Morako, who in turn claimed that he bought the chemical from Dom Azumuka. Mr. Azumuka, went on the run, but when caught by the police he led us to one Mr Adekunle, a storekeeper with VEEPEE Industries in Ota, Ogun State. Mr Adekunle confessed to have stolen drums of chemicals from VEEPEE. Laboratory analysis of the contents of the remaining drums revealed the chemical to be Propylene glycol monomethyl ether, which is an inedible and highly flammable chemical used in the production of printing ink. The only information we could get from the drums was that the chemical was made in Taiwan.

The suspects also revealed that Mr Chinwendu Morako dispensed all the stolen chemicals into unlabelled 40-litre containers using plastic buckets and funnels, before selling them on. It appeared that Mr Chinwendu Morako was the source of the Diethylene glycol. It may have been that these chemicals were resold in good faith, and Tranxell Limited might have inadvertently sold Diethylene glycol to Barewa Pharmaceuticals since the chemical was sold in unlabelled containers. However, the onus was on Barewa Pharmaceuticals to analyse all raw materials used in their production line, as well as the finished products before final release.

As I conclude this book, NAFDAC is still investigating and tracing the origin of this chemical that has caused the country so much sadness and almost threatened the trust and confidence that Nigerians have in NAFDAC.

To forestall a repeat of this ugly incident, we incorporated in our SOP, a ruling that all Propylene glycol to be imported into Nigeria must be recertified by our independent analysts in India and China before shipment. In countries where we do not have independent analysts, NAFDAC officials must certify all imported Propylene glycol before it is released from the ports or bonded warehouses, no matter how sophisticated the factory's quality assurance system might be. This has become necessary because the Diethylene tragedy has become a recurring decimal in the world and in Nigeria.

A quick summary of the recorded deaths worldwide due to inadvertent use of Diethylene glycol in drug formulation captures a frightening scenario: in 1937, 100 people died in the USA; from 1990 – 1992, 200 children died in Bangladesh; in 1995, 89 died in Haiti; in 1998, 30 died in India; in 1990, 200 children died in Ibadan and Jos in Nigeria after taking Paracetamol syrup produced with toxic Diethylene glycol solvent; and in 2008, we lost over 70 children to this chemical. We have also de-registered My Pikin and all other children's Paracetamol syrup or mixtures containing Diphenylhydramine or any anti-histamine due to the continuous abuse of the drug as a sedative for babies.

We have also encouraged university teaching hospital managements to always inform NAFDAC of such occurrences, especially since we have set up Pharmacovigilance Centres in these hospitals for reporting such situations. This is because if the affected hospitals had reported the deaths to NAFDAC through one of the Pharmacovigilance Centres, the number of fatalities would have been contained.

Closure of Onitsha Drug Market

The closure of the Onitsha Bridge Head Market, Anambra State, on March 6, 2007, was one of the high points of the Agency's continued war against the mass murder of Nigerians through the sale of counterfeit medicines and other substandard regulated products. The market has been there for decades, the main reservoir of counterfeit medicines in Nigeria and the point from which most counterfeit medicines are distributed. Most of the fake drug dealers in Nigeria were either trained in Onitsha or trained by people who were trained at Onitsha market. Consequently, we held several meetings with the executive members of the drug traders in Onitsha, to discuss the need for them to help us flush out the criminals among them and their counterfeit drugs from the market. They cooperated initially, leading us to the secret warehouses of the biggest drug counterfeiter in Nigeria at the time, Marcel

Nnakwe, and making him forfeit the counterfeit medicines in his warehouses for destruction and tender a public apology to Nigerians.

For about five years, we carried out periodic screening of market lines, carting away counterfeit medicines and burning them publicly. We also closed some lines for weeks, to enable us to conduct proper mopping-up of illegal medicines. As a result, the traders started to comply with NAFDAC directives. Their ability to resist inspections got whittled down. However, shortly after an Abuja High Court judge declined to allow the trial of several people suspected of an assassination attempt on my life – because of my unyielding resolve towards the fight to eradicate fake medicines in Nigeria – on account of lack of jurisdiction, the medicine sellers in Onitsha stopped cooperating with NAFDAC. That unfortunate ruling actually emboldened the drug counterfeiters, not only to resist our inspections, but also to attack our staff.

On June 3, 2006, our officers were physically attacked and driven out of Onitsha Bridge Head Drug Market, along with the 12 police officers that accompanied them. Six operational vehicles belonging to NAFDAC were also destroyed. It was a miracle that everyone escaped unharmed. The painful thing about the embarrassing level of counterfeit medicines in Onitsha is that the identities of the drug counterfeiters were not hidden. They did not wear masks when they attacked our staff, but the genuine drug dealers feared them.

The fake drug situation at Onitsha continued to deteriorate by the day, posing great threats to public health. A WHO/DFID study of the level of incidence of counterfeit medicines in Nigeria revealed that in all parts of the country, minus Onitsha, we had less than 10 per cent counterfeit drugs in circulation, but Onitsha had over 30 per cent and this brought our overall figure to 16.7 per cent. Even though that was a great improvement over the figures recorded by many researchers before 2001, which ranged from 41 per cent to 68 per cent, it was still unacceptable because lives were involved. When it became impossible for us to screen the market and remove the huge quantities of counterfeit medicines, we were left with no other option than to close it. Our team took up position by 3am on March 6, 2007. The team comprised 350 police officers, 150 soldiers and 150 NAFDAC staff. After the closure, we commenced shop-by-shop screening during which we found the following:

- Large quantities of counterfeited, faked and expired fast-moving and costly medicines.
- Large quantities of banned and smuggled drug products.

- Vaccines whose cold chain had been broken due to improper storage, giving rise to non-potent or virulent vaccines.
- Packaging materials and labels for various products belonging to several reputable companies such as May & Baker, Pfizer, GSK and Swipha.
- Bags of Indian hemp, which were handed over to the National Drug Law Enforcement Agency (NDLEA).
- Drugs donated by international agencies and the Nigerian Government for free distribution to the needy, which included High potency Vitamin A capsules, tuberculosis drugs and Coartem (antimalarial).
- Tablet punches used in making different types and shapes of tablets, as well as finished tablets. The fake tablets were actually ready for packaging.
- Five small manufacturing factories in the market, which manufactured children's syrups such as Paracetamol, Chloroquine, Multivite and cough syrups, labelled Made in Lagos. This illegal plant was dismantled.
- An illegal clinic in the market where injections and infusions were administered and abortions performed. This clinic was promptly dismantled.

On April 5, 2007, we publicly destroyed 104 truckloads of fake, counterfeit, expired, banned and smuggled drugs worth over ₦6.5 billion (US\$55,652,140).

Follow-up Action

We interrogated some members of the Board of Trustees and the Eradication Committee and some other key officials. Eight members refused to honour our invitation or absconded during investigations and gave us fake residential addresses. In their statements during interrogation, some members of the Board of Trustees and the Eradication Committee were evasive in answering questions put to them. For instance, they collected large sums of money from the traders after the attack on our officers, claiming that the money was for what they called "settling NAFDAC". To date they have neither disclosed the total amount collected nor accounted for it. It was inconceivable that anybody would have the courage to accept any "settlement" (bribe) in the new NAFDAC under my leadership.

Re-opening of the Market

During the three and a half months of the market closure, individuals, groups and organisations pleaded with us to re-open the market, considering the fact that not all the traders were criminals and that shops selling other commodities were also in the closed drug market. The Governor of the State, Mr Peter Obi, guaranteed that he would ensure that whatever conditions we gave for the re-opening of the market would be complied with. The market was re-opened on June 25, 2007 and the following measures were taken:

Immediate and Short Term Conditions for Opening the Onitsha Drug Market

1. The former Caretaker Committee and Eradication Committee were disbanded and new ones appointed.
2. Members of the Caretaker Committee would sign a letter of undertaking to be of good conduct.
3. It would be the responsibility of the new Caretaker Committee to hand over to NAFDAC the eight members of the Board of Trustees and Eradication Committee or former officials of the Onitsha Patent and Proprietary Medicine Dealers Union (OPPMDU), who either refused to honour our invitation, or absconded during the interrogation.
4. Following our interviews, interrogations and other findings, which seriously indicted some people, we decided to ban members of some of the previous committees, trustees and other officials of OPPMDU from owning any shop or operating inside the Bridge Head Drug Market.

We also identified kingpins of faking and counterfeiting in the market and the established importers of China-cloned fake and counterfeit drugs known to the traders, some of whom were known by name to NAFDAC. The new Caretaker Committee members and the rest of the traders were to ensure that the new measures established were implemented and adhered to.

5. The kingpins of faking and counterfeiting and the owners of the various shops, who were generally responsible for the monumental mess in the market, were banned from operating in the market. They were given 48 hours to remove all their belongings from the shops and were thereafter never to transact any business in the drug market.

Apart from banning the shop owners from the market, we demanded that the caretaker committee assist us in apprehending all the people involved in the fake drug trade in the market.

We also insisted on the following:

1. There should be no production, mixing or manufacture of any type of drug in the market;
2. There should be no sale of any type of vaccine or controlled drugs in the market;
3. There should be no surgical operation or any illegal clinic in the market.

Long-Term Conditions

NAFDAC demanded:

1. Construction of a fence around the drug market with a maximum of three entrances;
2. Complete redesigning or restructuring of the shops, to make them suitable for drug storage;
3. Provision of adequate electricity supply to the market.

Even after satisfying the short and long-term conditions, the present market would still be unsuitable for drug sale because of the high temperature in the shops. The ultimate solution would be for the Anambra State Government to allocate land for the construction of a modern Drug Mart that would be registered by the Pharmacists' Council of Nigeria (PCN), supervised by pharmacists and monitored by NAFDAC personnel. In this regard, the Governor of Anambra state publicly announced that he would build a modern drug market to relocate the dealers as a long-term plan.

As soon as the market was re-opened, all the traders were asked to clear out any expired drugs remaining in their shops and voluntarily hand them over to our officers. Failure to comply would result in severe sanction of the shop owner. The police and soldiers remained for another two days to ensure that no drugs were removed from the market until our team had evacuated all expired ones.

The new caretaker committee of 12 (originally 13, but one died), proved ineffective for the job and was therefore dissolved on May 21, 2008, barely a year after the market was re-opened. A new Caretaker Committee comprising 15 members was sworn in on May 28, 2008.

Closure of Ariaria Drug Market in Aba

Surveillance reports in June 2002 indicated the presence of large volumes of fake and substandard drugs in Ariaria Market, Aba. A team of the Federal Task Force on fake and counterfeit drugs was therefore dispatched to the market to identify and remove all such products. When our officers got to the market on June 13, the traders tried to bribe them, but this failed. The traders, consequently, became hostile and pelted our officers with bags of sachet water, thereby preventing the team from carrying out their assignment. On June 21, 2002 in collaboration with the Nigerian Police Force, we shut down the market. The affected traders urged the then Governor of Abia state, Dr Orji Uzor Kalu, to intervene. They assumed that because the Governor was up for re-election the following year and needed their votes, he would take their side, but to their surprise, the Governor told them to comply with whatever NAFDAC directed. The closure lasted for over three months and the market was re-opened only after the affected traders advertised their apologies and pleas in the print and electronic media. They pledged to obey all NAFDAC regulations. When we re-opened the market in September 2002, we carried out a six-day shop-to-shop screening exercise, during which fake, counterfeit and substandard drugs, worth over ₦330 million (US\$2.87 million) were removed and publicly destroyed.

Closure of Sabon Gari Drug Market in Kano

In July 2004, we closed Sabon Gari market in Kano, following reports of the presence of large quantities of counterfeit medicines. The traders appealed to the Emir of Kano, His Royal Highness, Alhaji (Dr) Ado Bayero, to prevent NAFDAC from taking the necessary action. The Emir declared that he would never support illegality and urged the traders to comply fully with our directives. Thereafter, the traders lobbied the Governor of Kano State, Mallam Ibrahim Shekarau, who was elected to office representing the All Nigerian People's Party (ANPP), an opposing party to the ruling People's Democratic Party (PDP), under which I was appointed the Director General of NAFDAC. The traders alleged that the PDP was using the office of the Director General of NAFDAC to shut down their market. By doing this, they were hoping to appeal to the opposition sentiments of the ANPP-led Kano State Executive, making food and drug safety a polarising political issue. Governor Shekarau refused to assist the traders and even went further, telling them that food and drug regulation transcends party politics. Disappointed, they came back to assist our enforcement officials to close the market, without any further resistance. The market was closed for three months.

Contaminated Infusions Produced by Biomedical Services Company Limited

Biomedical Services Company Limited, Ilorin, Kwara State, is the first indigenous infusion-producing factory in Nigeria. At various times between 1997 and 2001, NAFDAC records showed that Biomedical's infusions were found to be contaminated with mould and/or other microorganisms.

- a. In 1997, physical examination of several bags of Biomedical's infusions revealed mould growth.
- b. In 1998, Petroleum (Special) Trust Fund (PTF) reported that Bioflex blood bags from Biomedical were leaking. They had poor general appearance, looked cloudy and contained gas bubbles. They were therefore, dangerous for blood transfusions.
- c. In 1999, PTF again reported mould growth in Hartman's solution (Ringer's lactate infusion), another product from Biomedical Services Company Limited.
- d. On November 11, 2001, NAFDAC received a consumer complaint from the University of Nigeria Teaching Hospital (UNTH), Enugu, regarding three patients who had reacted adversely to infusions manufactured by Biomedical Services Company. The patients had severe rigour, vomiting, sweating, restlessness, seizures and impaired levels of consciousness. The reactions stopped once the administration of the infusions was discontinued. NAFDAC investigations revealed that three batches of Biomedical infusions were heavily contaminated. This prompted a NAFDAC team to inspect Biomedical's factory to evaluate their Good Manufacturing Practice (GMP). The following lapses were found:
 - i. There were no qualified or experienced staff in infusion production. The company had no single production pharmacist between May and October 2001. The most senior production staff member was a mathematician.
 - ii. Supervision of production processes was inadequate.
 - iii. Infusions were produced and kept unsterilised for four days, which provided perfect conditions for microbial and fungal growth.
 - iv. Sterilisation of 500ml and 1000ml pack sizes of infusions were done in the same autoclave at the same time, leading to inadequate sterilisation of the products.
 - v. Water treatment processes for the water used in the production were grossly inadequate.

Consequently, the factory was shut down in January 2002, and they were directed to comply with minimum acceptable standards required for the production of infusions. After the company had complied with the directives, the inspectors put a routine inspection process in place to ensure that compliance was maintained and new lapses did not emerge. In addition, initial samples were retrieved from the production line for laboratory examination in order to verify that the products from the new factory environment were sterile and Pyrogen-free. The facility was re-opened in September 2002. NAFDAC also ensured that all necessary facilities and the right calibre of staff were employed in their manufacturing processes. NAFDAC permitted the re-opening of the factory for commercial production on the condition that GMP standards must be maintained at all times. Biomedical Services was not financially sanctioned at that point despite the huge resources we expended on collecting samples, testing and re-certifying the company and its operations. This was done to reduce the burden on the company and promote our policy of encouraging local manufacturers to grow and thrive.

Unfortunately, between January and March 2004, we received more disturbing reports of adverse reactions in many patients caused by Biomedical's infusions at the Abdullahi Wase Specialist Hospital Kano, VOM Christian Hospital, Jos and Federal Medical Centre, Yola. The following infusion batches were implicated in the reports:

- a. 10 per cent Dextrose; (batch number 103312).
- b. 0.9 per cent Sodium Chloride; (batch number 103320)
- c. 5 per cent Dextrose; (batch number 093260)
- d. 5per cent Dextrose/0.9 per cent Sodium Chloride. (batch number 113333).

Laboratory analysis of samples of infusions collected from the factory showed that two other dextrose infusions were also heavily contaminated:

- a. 5 per cent Dextrose 500ml (batch number 103307)
- b. 10 per cent Dextrose 500ml (batch number 083229).

It was evident that the management of Biomedical Services Company Limited had prior knowledge of these lapses, because they wrote to some of their distributors asking them to return the contaminated infusions, while ignoring others such as retail outlets, hospitals and clinics.

Immediate recall procedures were initiated to prevent any further casualties. After the recall, the Managing Director of Biomedical Services visited our office and was informed of our findings. We reiterated our desire to assist local manufacturers in every way that we could. We offered to send NAFDAC pharmacists to the factory, at no cost to them, to trace the sources of the contamination and to find out what changes needed to be made in order to forestall future occurrences of such serious lapses. We demanded the repayment of the sum of ₦3,613,090 (US\$31,418), being the costs we incurred for the recall. In his response, he requested that all the costs associated with the alerts be waived.

One may wonder why such a company was allowed to remain in operation. The following were the reasons:

1. 10 out of the 13 registered products produced by Biomedical were of good quality while three were contaminated and unsafe for use.
2. We needed to assist in the growth of local drug production as a means of fighting drug counterfeiting, since most counterfeit drugs are imported.
3. We appreciated that closure of factories worsen the high unemployment situation.

After due consideration, we shut down Biomedical again and once more offered to assist them to put their factory in order. Apart from the corrective measures taken to halt the flow of unsafe Biomedical products into the market, it is important to note that NAFDAC did not levy any monetary or other administrative penalties against Biomedical Services for producing substandard infusions. That notwithstanding, Biomedical filed a lawsuit seeking a permanent injunction and compensatory damages against NAFDAC for the factory closures. However, the suit was successfully contested by NAFDAC at the Federal High Court, Ilorin, and their claims were dismissed. Consequently, the company followed through with all our directives and paid the amount incurred for the recall of their products. Their factory was then reopened.

Contaminated Infusions Produced by DANA Pharmaceuticals Limited

Following the Biomedical case, there were two reports of contaminated infusions in circulation involving DANA Pharmaceuticals Limited, an infusion and other medical products company based in Minna, Niger State. At this time, NAFDAC already had a Standard Operating Procedure in place. In accordance with the SOP, DANA's controlled products

manufacturing plant was shut down and compliance directives were issued. The factory was re-opened after it had complied with the directives without hesitation. In addition, the company, on its own initiative, shut down the factory again for months in order to implement a comprehensive overhaul and upgrade of the manufacturing processes and environment. DANA's approach towards change was very thorough and impressive and has become a model which NAFDAC recommends to many other pharmaceutical companies and manufacturers. The second report of infusion contamination again involving this company came after the overhaul of its factory. Investigations revealed that the contamination was not because of manufacturing defects but due to poor storage conditions. Tests from all the retention samples recovered from DANA's factory showed no sign of contamination. Hence, poor product handling or storage at any point along the distribution chain could have caused the contamination. For this reason, we did not issue a fine against DANA Pharmaceuticals or shut down the production plant again.

Fake and Contaminated Water for Injection

Following reported cases of contaminated infusions between October and December 2003, we decided to conduct a nationwide surveillance and sampling of water for injection in circulation in Nigeria. Out of the 149 brands tested within this period, only two were microbial and Pyrogen-free. We took immediate steps to address the situation: first, we publicised the two safe brands of water for injection. We also requested all distributors and retailers still in possession of the contaminated brands to submit them to the nearest NAFDAC office for destruction. Subsequently, we removed the poor quality brands in circulation. Secondly, we encouraged the two companies whose brands passed our tests to import large quantities of the products to forestall scarcity. The two certified brands were:

- Sam Pharmaceuticals Water for Injection (NAFDAC No. 04-0662) –manufactured by Vifor Pharmaceuticals and distributed by Sam Pharmaceuticals Limited; and
- Salimpex Water for Injection (NAFDAC No. 04-2643) – manufactured by Pharmaceutical Solutions Industries and registered by Salimpex Limited.

Thirdly, we encouraged drug manufacturers and importers to engage in massive importation of genuine water for injection by allowing them to import without registration over a specified period, as registration was ongoing. We also waived all laboratory fees. However, all imported water for injection was tested before the importers were allowed to distribute it.

In August 2005, at Onitsha, our Enforcement Officers mounted a raid and confiscated hundreds of thousands of ampoules of fake water for injection from an illegal factory. The owner was absent at the time of the raid, but the factory was in full production with 10 workers on duty. All the production rooms were locked from the outside with padlocks, to give the deceptive impression that there was nobody inside. This was a clear indication that the owner and the workers were fully aware of the fact that their operation was illegal. Results of the laboratory tests carried out on the seized water for injection revealed that they were not sterile and were contaminated with Pyrogens. The factory was closed down and the equipment was confiscated and destroyed.

In another development, we apprehended one Mr. Cyril Okeke in Okpoko, Onitsha on April 24, 2008 while he was filling empty injection vials labelled Made in India with ordinary water! He confessed to the crime on arrest and interrogation and was subsequently prosecuted. In July 2008, the Federal High Court, Awka sentenced him to five years imprisonment. Justice Peter Olayiwola who delivered the judgement remarked on the seriousness and enormous magnitude of the crime.

Again, another case of unsterile injection water being sold to the unwary public was uncovered through a consumer complaint received at NAFDAC's office in Asaba, Delta State. This member of the public reported the sale of an unregistered energy boost drink by Dean Pharmaceuticals, Asaba. NAFDAC carried out investigations, which revealed that the company was also producing Dean water for injection using unqualified staff under very poor GMP. We also discovered that the production date of 09/2006 on the water was inconsistent with the actual manufacturing date of 05/09/2008. We confirmed that they were also producing unwholesome oral drip and energy boost drink.

Dean Pharmaceuticals had applied for re-inspection of their production facilities for approval to produce the water for injection. Inspection of the premises was done on February 22, 2008 and the company was found to be unfit for the manufacture of sterile products. The company was issued with a compliance directive to rectify the lapses, inform NAFDAC and seek approval before commencing production. They did not do any of these; instead, using unskilled personnel, they commenced production and distribution of Dean water for injection under conditions unfit for production of sterile products. The managing director was arrested and he confessed to the crime. The factory was closed down and the case was handed over to the Enforcement Directorate of NAFDAC for prosecution.

Nationwide Crackdown on Importation and Distribution of Fake Halfan (Halofantrine) Anti-malarial Tablets

In March 2004 GlaxoSmithKline reported the widespread circulation of fake versions of Halfan, a popular anti-malarial drug manufactured by the company. In line with our standard operating procedure, all NAFDAC state offices were directed to embark on a nationwide removal of the fake Halfan from all markets, warehouses and drug selling outlets.

On the first day of the raid, we confirmed that the fake Halfan tablets, with batch No. 735 and manufacturing and expiry dates of January 2003 and January 2006 respectively, were imported from China. This fake batch had already been distributed and was being sold all over the country. From our investigations, the importers of the fake Halfan products were traced to Onitsha Head Bridge Market in Anambra State and the Idumota Drug Market in Lagos. There were four major importers, two based in Lagos and two in Onitsha.

One of the importers, Mr Okechukwu Obiefuna, had been linked to the importation of counterfeit medicine in the past. After the interception of his consignment of fake Halfan and other counterfeit regulated products, he adopted several tactics to avoid being caught. Mr Obiefuna went underground and paid another person to be his alibi. This deception was uncovered and the alibi witness, Mr. Christopher Ochumba, was arrested. It took us nearly seven weeks to apprehend the Mr. Obiefuna.

Laboratory analysis of the fake Halfan tablets showed the active ingredient (Halofantrine hydrochloride) content was only 16.16 per cent. At both the Onitsha Head Bridge Market and the Idumota Drug Market, the genuine Halfan was sold for ₦720 – ₦800 per packet of 6 x 250mg tablets while the fake Halfan was sold for ₦150 - ₦250. However, both the original and the fake Halfan were sold for the same price at pharmacies and other retail outlets. The total quantity of fake Halfan recovered was 10,078 packets of 6 x 250 mg tablets. 10,000 packets of 6 x 250mg were recovered from Mr Obiefuna, while 78 packets were recovered from other sources. From the records available to us, the total quantity of fake Halfan imported initially into the country was 16,300 packets. The main importers absconded from Nigeria before arraignment at the Federal High Court.

Seizure of Two 20ft Containers of Counterfeit Medicines Imported by Landmark Industries Limited

Landmark Industries Limited, a company based in Ikeja, Lagos, imported counterfeit medicines valued at about ₦200 million (US\$1.74 million). The containers with the fake

drugs came aboard Maersk line and were discharged at Apapa Ports and transferred to Kirikiri Lighter Terminal (KLT), Lagos. The shipping manifest declared the contents as 1995 automobile spare parts. Having successfully passed through customs, the clearing agent who was handling the transaction approached NAFDAC officials at KLT to authorise the delivery of the containers without inspection. Our officials insisted that the containers must be opened for examination. With persistence from our officers, one of the containers (MSKU 224869–2) was examined on January 16, 2004 and was discovered to contain cartons of Panadol Extra. Immediately after the discovery, the clearing agent took to his heels. The Panadol Extra, obviously imported, was labelled Manufactured by SmithKlineBeecham Nigeria Plc. This product was found to be counterfeit. In view of this, NAFDAC issued seizure notices for the two 20-foot containers. The two containers were evacuated to our warehouses, where full physical examination revealed the following contents:

Container number MSKU 224869–2:

Panadol Extra Tablets (Analgesic)

Quantity: 100 cartons x 100 x 200 caplets

Batch number: 042

Manufacturing date: 07/2003

Expiry date: 07/2006

NAFDAC Reg. No.: 04–0005

Manufactured by: SmithKlineBeecham Nigeria Plc (RC 8726), 51 Town Planning Way, Ilupeju Industrial Estate, Ilupeju, Lagos.

NGC Valgin Tablets (Analgesic)

Quantity: 150 cartons x 140 x 1000 tablets

Batch number: LO96

Manufacturing date: 03/03

Expiry date: 03/08

NAFDAC Reg. No.: 04–2372

Manufactured by: Nigerian German Chemicals Plc, Km 38 Abeokuta Expressway, Otta, Ogun State, Nigeria.

Glanil (Glibenclamide) Tablets (Antidiabetic)

Quantity: 20 cartons x 500 x 100 tablets

Batch number: AO21

Manufacturing date: 11/2002

Expiry date: 11/2005

Manufactured by: Nigeria German Chemicals Plc, Km 38 Abeokuta Expressway, Otta, Ogun State, Nigeria.

Container number TTNU 390005–1:

Sulphatriad Tablets (Antibiotic)

Quantity: 83 cartons x 60 jars x 500 tablets

Batch number: IR575

Manufacturing date: 09/2003

Expiry date: 09/2008

NAFDAC Reg. No.: 04–0322

Manufactured by: May & Baker Nigeria Plc, 3/5 Sapara Street, Industrial Estate, Ikeja, Lagos, under licence from Aventis Pharma.

Oruvail 200 Capsules (Anti-arthritis)

Quantity: 21 cartons x 100 boxes x 10 packets x 272 capsules

Lot: IR35

Manufacturing date: 05/2003

Expiry date: 05/2006

NAFDAC Reg. No.: 04–0017

Packed by: May & Baker Nig. Plc, 3/5 Sapara Street, Industrial Estate, Ikeja, Lagos.

Amoxyl 500mg Capsules (Antibiotic)

Quantity : 30 cartons x 100 boxes x 10 x 10 capsules

Batch number: 209

Manufacturing date: 03/2002

Expiry date: 03/2007

NAFDAC Reg. No.: 04–2481

Manufactured by: Medreich Sterilab Limited, Virgonagar, Bangalore, 560049, India.

Postinor Tablets (Oral contraceptive)

Quantity: 49 cartons x 200 boxes x 10 tablets

Batch number: T8A082B

Manufacturing date: 08/2003

Expiry date: 08/2004

Name and Address of Manufacturer: Not indicated

Flagyl 400 Tablets (Antifungal)

Quantity : 50 cartons x 200 boxes x 20 x 10 tablets

Batch number: 1332

Manufacturing date: May 2001

Expiry date: May 2006

Manufactured by: Rhone–Poulenc (India) Limited, (Formerly May & Baker (India) Limited), D–5 MIDC, Palthan 431 148, Dist. Aurangabad.

Flagyl 400 Tablets (Antifungal)

Quantity: 500 cartons x 30 x 10 tablets

Batch number: P3014

Manufacturing date: Mar 2003

Expiry date: Feb 2007

Manufactured by: Nicholas Piramal India Limited, Plot No. 67–70, Sector 2, Pithamper 454775 Dist Pharm, Madhya Pradesh, India.

It is interesting to note that five out of the nine products were labelled Made in Nigeria, although they were all imported from India. This is a case of counterfeiting of the products of multinational companies operating genuine businesses in Nigeria. Most of the drugs were Prescription Only Medicines (POM), used for the treatment of serious health conditions such as diabetes, rheumatoid arthritis and bacterial infections. The seized products were subsequently destroyed publicly. The perpetrators and their nefarious activities were publicly exposed as a deterrent to others.

Seizure of Fake Pharmaceutical Products Imported at Lagos Airport

On April 28, 2008, at the Murtala Mohammed International Airport, Lagos, we seized a consignment comprising five packages of fake contaminated Betnesol-N eye/ear drops and fake Dano Tetanus toxoid injection, which came aboard a Virgin Atlantic cargo flight. It is important to emphasise that Tetanus toxoid is a vaccine that is supposed to be transported in an unbroken cold chain. In this case, the vaccine was transported as any other cargo, without regard to maintaining the cold chain. When the cold chain of such vaccines is broken, they can become harmful. The importer, ‘one Mr. Olisaemeka’, was handed over to our Enforcement Directorate for necessary sanctions. Despite all efforts, he refused to reveal his true surname and address. The drugs were destroyed publicly.

Seizure of a 20ft Container of Fake Pharmaceutical Products

Following a tip-off from one of our secret informants, we monitored a vessel carrying fake pharmaceutical products even before its arrival in Nigeria. This led to the seizure of a 20-foot container of fake pharmaceutical products worth about ₦133 million (US\$1.16 million). The seized cargo which comprised assorted counterfeits of fast-moving brands of multinational companies such as GlaxoSmithKline(GSK), Merck Sharp & Dohme and Reckitt Benckiser, included drugs such as antibiotics, antihypertensives, antidiabetics and antiasthmatics. The container, MSKU 2656523, came aboard a Maersk vessel which berthed at Apapa Port, Lagos, on May 15, 2008. Based on the tip-off, on May 8, 2008, we issued a “Hold” notice for the container to the Nigerian Customs Service, APM Terminals and Maersk Line. While the container was on hold, something strange happened that could have resulted in its fraudulent release. On May 20, 2008, while the container was positioned for examination, the NAFDAC officer who was stationed to monitor its movement suddenly

noticed that the seal on the container had been broken, and shortly after a padlock had been put on it to give the erroneous impression that the container had undergone the necessary physical examination by both NAFDAC and Customs and was, therefore, ready for release, when, in fact, it was not! As is our procedure in such situations, we immediately issued a Seizure notice and Request for Examination of the container to the Nigerian Customs Service. As a follow-up, we wrote to the Customs' Deputy Comptroller at the APM Terminal. He was amazed when informed that the container was yet to be examined. None of his examining officers accepted responsibility for breaking the seal or fixing the padlock. What was most shocking at this point was that their records revealed, to their apparent surprise, that the container had actually been released on May 15, 2008, the very day the vessel berthed at Apapa Port. This meant that the container was manifested to have been released from the Port even before it was unloaded from the vessel! This development led us to issue an immediate evacuation notice to the Customs, APM Terminals, Maersk Line and the Nigerian Ports Authority. It is very interesting to note that nobody owned up to being the clearing agent for the container. Upon scrutiny, the Single Goods Declaration (SGD) Form was found to bear forged NAFDAC stamps and signatures. It also bore false names of importer and manufacturer. The name of a respectable company, Embassy Pharmaceuticals and Chemicals Company Limited, was fraudulently listed as the importer, but the shipping manifest showed the importer to be B.K.B. Enterprises of Head Bridge, Onitsha. The name of the clearing agent stated on the SGD Form was Becon & Stat West Africa Limited. Investigations on the activities of this agent and his reported collaboration with some customs officers is still ongoing as at the time of concluding this book.

***Two 20ft Containers of Pharmaceutical Products Under NAFDAC Seizure
Auctioned by the Nigerian Customs Service***

On March 28, 2003, NAFDAC inspectors intercepted four trucks carrying four 20-foot containers (SEAU 2303545, CMBU 2388849, TTNU 3668481 and TTNU 2453956) attempting to leave Adekunle Way Container Terminal, Apapa Port, Lagos, without physical examination. The containers were prevented from leaving the port following a complaint from our officials to the Nigerian Customs Service and the Nigeria Police Force, Apapa Port. The Nigerian Customs Service released two of the containers (SEAU 2303545 and CMBU 2388849), which contained pharmaceutical products, but were manifested to contain automobile spare parts. In order to prevent the containers from being smuggled out, we

issued a Seizure notice dated March 29, 2003. The Customs Service responded, through a letter dated April 2, 2003, that they had already seized the containers.

We later learnt that some officers of the Nigerian Customs Service sold out the contents of the containers without reference to NAFDAC. Some 531 cartons of Novalgin tablets and 564 cartons of Napfen (Ibuprofen) tablets were sold to one Alhaji Isa Bamanga based in Kaduna, while 564 cartons of Napfen (Ibuprofen) tablets were sold to one Mrs Roseline Ochai in Surulere, Lagos. Efforts to recover these products proved abortive. Apparently, they had been sold on.

One of the auctioned products, Novalgin, contained Dipyrone, which was a banned drug in Nigeria. In addition, detailed information on the drugs, including the name of the manufacturer, batch number and manufacturing and expiry dates, were not stated on the products, and this is typical of counterfeit medicine. The quality, safety and efficacy of the products could therefore not be guaranteed.

In yet another case, eight containers (1 x 40ft and 7 x 20ft) manifested as motor spare parts, flash lights and general merchandise were held at the Onne Port in Rivers State as initial inspection showed they contained pharmaceuticals. They were released by Customs without undergoing full inspection by NAFDAC and without our authorisation. Six of the containers were removed from the port in November 2003, one in December 2003 and the last one in January 2004. In each of these instances, we wrote protest letters to the Nigerian Customs Service but the letters were ignored.

Julius Berger Pharmacies Shut Down

We received a complaint from a man concerning a drug he obtained for his sick daughter from the Daughters of Charity Hospital, Abuja. He was given Chloroquine, Paracetamol and Co-trimoxazole to administer to the child. He complained that the Co-trimoxazole suspension was changing colour and caking, and that the child's condition deteriorated with the administration of the medicine. Consequently, we visited Daughters of Charity Hospital to confirm the report and determine the source of the drug. Daughters of Charity reported that they bought the drug from Julius Berger, a German multinational construction company operating in Nigeria, and tendered a receipt with which the drug was purchased from the company as evidence. With this receipt, we went to the company's clinic in Abuja, to confirm and investigate the report. NAFDAC investigations revealed that Julius Berger clinics were importing and stocking large quantities of unregistered drugs, without NAFDAC permits,

supposedly for their internal use. It was also confirmed that they were re-selling some of these drugs to the Daughters of Charity hospitals and clinics. They also operated two different pharmacies, one for the expatriate workers and the other for the Nigerian employees. The pharmacies were operated without a Superintendent Pharmacist.

In the pharmacy for their Nigerian employees, they stocked Dipyrone injection (which had been banned by NAFDAC due to its severe adverse drug reactions). They also imported and stocked drugs made by Sinochem Ningbo, a Chinese drug company that was blacklisted by NAFDAC in 2002, for exporting counterfeit medicines to Nigeria. Counterfeit medicines manufactured by this blacklisted Chinese company, recovered from Julius Berger's pharmacy included: Frusemide injection; Co-trimoxazole powder for oral suspension; Ferrous sulphate tablets; Vitamin B-Complex injection; Chloramphenicol eye drops (0.5 per cent); Amoxicillin sodium injection; Metronidazole injection; Diclofenac sodium injection; Promethazine hydrochloride injection and tablets; Tetracycline eye ointment; Ibuprofen tablets; Hydrocortisone acetate; Diclofenac 1 per cent gel and Hyoscine hydrobromide injection. The most painful thing about this case was that the company's construction business has so flourished in Nigeria, due to sustained patronage by Nigerians and the Nigerian Government that they could certainly afford to treat their Nigerian employees better.

All the unregistered and counterfeit medicines found in their pharmacies were removed for destruction. Laboratory analysis of the drugs confirmed their unsuitability for human use and as a result, we extended the investigations to all the other Julius Berger clinics in Lagos, Port Harcourt, Warri, Agbor, Bauchi and Calabar. Following the investigations, all the company's pharmacies and clinics across Nigeria were shut down and we issued them with compliance directives.

On May 19, 2006, the pharmacies were re-opened after they complied with all our directives, paid the stipulated fine and tendered a written apology. They have now employed qualified pharmacists and stopped discriminating between their Nigerian and expatriate employees in dispensing drugs.

NAFDAC Closes Hospital in Lagos for Using Analgin Injection

A man whose wife collapsed and died after receiving Analgin injection, which is a banned product, reported the incident to my office. Our officials visited the hospital, Peculiar Medical Centre, Hospital and Maternity, Lagos. The owner of the hospital, "Dr A.O. Ogunjimi", who claimed to be a medical doctor, administered the Analgin injection to the patient on

August 17, 2006. Upon further interrogation, he admitted that he was not a medical doctor. He was then arrested for administering a banned product on a patient. Our officials also questioned “Dr Olasunkanmi Sunday”, who posed as a patient. He was also arrested and both of them handed over to law enforcement agencies for thorough investigation and possible prosecution. Consequently, the illegal hospital was shut down. The husband of the victim wrote a letter of appreciation to NAFDAC, thanking the Agency for helping to bring the person who caused his wife’s death to book.

Importation of Unregistered Fake Products and Other Violations by Orange Drugs Limited

In January 2006, officers of the Nigerian Customs Services stopped a truck, belonging to Orange Drugs Limited, that was transporting pharmaceutical products from Lagos to Onitsha. The customs officers invited NAFDAC agents, who on examination of the cargo discovered the following unregistered pharmaceutical products:

Beauticyn Cream – 250 cartons

Beytucen Cream – 916 cartons

Boska Tablets – 145 cartons

The Beauticyn cream was unregistered and labelled as being manufactured by Medipharco in Hue, Vietnam, when it was actually imported from Indonesia.

The Beytucen cream was also not registered and was labelled as manufactured by Mega Pharma GMBH, West Germany. Mega Pharma GMBH ceased to exist after the re-integration of East and West Germany. Earlier, in May 2004, NAFDAC had issued a permit to Orange Drugs Company Limited to import 50 cartons of Beytucen from Indonesia for registration purposes. The registration was not concluded before the violation. 916 cartons of Beytucen cream were actually imported, far in excess of the 50 cartons approved for importation and registration. They were packed behind the Boska tablets, which had been duly registered. The products were confiscated. When questioned, senior officers of the company claimed ignorance of the importation. Following several meetings held between NAFDAC and Orange Drugs Limited, their management wrote us an apology letter. They explained that the shipment was due to a mix-up from their manufacturers who sent a letter of undertaking assuring NAFDAC that this will not happen again. Orange Drugs Limited was issued an administrative fine of ₦1 million (US\$8,696) and asked to write a letter of consent to

forfeit the 916 cartons of Beytucen cream and 250 cartons of Beauticyn cream for destruction. The company complied by paying the administrative fine and forfeited the fake products for destruction. The case against Orange Drugs Limited was withdrawn from the court following the out-of-court settlement.

The Oral Polio Vaccine (OPV) Controversy

The quality, safety and potency of vaccines as prophylactic agents are important to NAFDAC and to the Federal Government. The regulation and control of the importation, exportation, manufacture, advertisement, distribution, sale and use of vaccines and biologicals are within NAFDAC's mandate.

The regulation of vaccines is highly complex and demanding, and therefore requires special consideration. Vaccines differ from other therapeutic medicines because of their sources: the products, the raw materials used in production and the biological methods used for testing are inherently variable in nature.

In 1993, several State governments and Islamic organisations in Nigeria refused to participate in the National Polio Immunisation campaign. They claimed that the Oral Polio Vaccine (OPV) was contaminated with the HIV virus and contraceptive steroidal hormones such as HCG, Oestradiol, Progesterone, Alpha-Ethinylestradiol and Testosterone. They believed that the Nigerian Government conspired with international organisations, certain religious groups and foreign governments to slow the growth of Islam in Nigeria through a systematic decimation of the Muslim population using the HIV virus and contraceptives. This allegation was widely accepted amongst the Muslim population and this created serious concerns for the Federal Government. As the controversy grew, both sides tried emphatically to reach out to the communities to advance their argument.

Due to the complexity and variability of vaccines, the WHO recommends that the manufacturer's quality tests be reviewed with possible complementary testing by national regulatory authorities, before the products are released for use. As a matter of protocol, NAFDAC reviews the manufacturer's quality tests following WHO recommendations and conducts the following compendia (standard routine) tests – physical appearance, identification, pH test, potency test, sterility test and stabilant content on all vaccines received either from the National Programme on Immunisation (NPI) or from local importers. After testing the vaccines, they are released on a lot-by-lot basis and each lot is approved for distribution after meeting specific control requirements for its type as specified by various

pharmacopoeia and other official international reference books. Screening for the presence of HIV, HCG or steroidal hormones is not routine, unless for the purposes of investigations arising from public complaints and concerns.

Despite NAFDAC's effort at screening all vaccines before they are released to ensure quality and safety, Jama'atu Nasril Islam's anti-OPV campaign gained momentum, with some State Governments totally boycotting the immunisation of children in their states. This situation escalated when some people alleged that the WHO, UNICEF, Rotary International and others deliberately added harmful substances to the OPV.

Some groups embarked on testing all the OPV stockpiles in their communities. Committees of experts were set up by Jama'atu Nasril Islam and various State Governments to ascertain the contents of the vaccines against the backdrop of the claim that they contained the HIV virus and contraceptive agents. The following were some of their claims:

1. **The National Hospital, Abuja:** Seven tests were conducted for steroidal and reproductive hormones (LH, FSH, Progesterone, Testosterone, Prolactin, HCG and Oestradiol). They reported that the samples tested negative to five of the hormones namely; LH, Prolactin, FSH, Progesterone and Testosterone. The National Hospital report also showed that the samples tested trace positive to Oestradiol, while three out of 12 samples tested trace positive to HCG.
2. **Dr Rafindadi, Pathologist, Ahmadu Bello University, Zaria:** His team, consisting of experts from chemical pathology, morbid anatomy and the microbiology units at ABU Zaria, used routine methods for the assay of HIV antibodies, Anti HBV, Anti HCV, TB, sedimentation rate for foreign cells, Oestrogens, Progesterone, Prolactin and common bacteria. The results were reported to be negative.
3. **Peak Laboratories** – a private laboratory: A team comprising Professor Isa, Dr Garba and Dr Mukhtar of Ahmadu Bello University Zaria, conducted the tests for the Kaduna State Government. The team reported that their samples tested positive to most of the Gonadotropins (hormones which stimulate the ovaries and testes), but negative to Prolactin. Their stated analytical technique was based on ELISA, a method known for its accuracy.
4. **Kano State Government:** The team in Kano, headed by Dr. Lawan Alhassan Bichi of Bayero University, tested samples at the Mallam Aminu Kano Teaching Hospital using

the Elesky 1010 method. They reported the presence of Gonadotropins and contraceptive hormones.

5. **Dr Kaita, Dean, Faculty of Pharmacy, Ahmadu Bello University, Zaria:** The tests were ordered by the Jamma'atul Nasril Islam Headquarters, Kaduna. Dr Kaita's results came from his work in Zaria and in India. He reported the presence of contraceptive hormones.

When these results were made public, critics of the NPI programme used every available media to attack the Federal Government and the leadership of the NPI. The issue escalated to a serious security threat for the Federal Government, leading to the intervention of the then President of Nigeria, Chief Olusegun Obasanjo, who directed that a team of eminent scientists be constituted to investigate the claims.

NAFDAC's Intervention

I considered this a personal challenge. I knew that it was critical at this point to make a statement that would instill confidence in the NPI programme and avert the looming political controversy that could degenerate into a national crisis. Moreover, NAFDAC tests and certifies all vaccines before they are administered by the NPI. I informed Nigerians through the media that the vaccines were screened and were safe. I even went as far as telling the public that if I had a baby I would have the baby immunised with any of the vaccines, because I was sure of NAFDDAC's test procedures and the safety of the vaccines. I gave these assurances because I believed in them wholeheartedly. To an extent, the public reassurance worked, largely because NAFDAC enjoyed unprecedented credibility. For added reassurance, I took the following two urgent actions:

1. Instructed the NAFDAC vaccine quality control laboratory to re-evaluate all OPV quarantine samples for the presence of HCG, Progesterone and Oestradiol;
2. Directed all state offices to draw OPV vaccine samples from their available stocks for re-evaluation.

The 20 out of 46 quarantined samples randomly drawn from both NPI and private companies and screened in our laboratory showed the following results:

- **HCG: Using test kits, the result was negative.**

- **Oestradiol and Progesterone: Using the High Performance Liquid Chromatograph (HPLC) techniques, Oestradiol was negative and Progesterone was present in low levels.**

We confirmed the presence of hormones but did not have the instruments to quantify them. More research would be needed to conclusively evaluate the OPV and resolve the controversy.

International Confirmations

We needed to identify laboratories abroad that would collaborate with us in conducting confirmatory tests and quantitative analysis of the identified contaminants. At the same time, the Federal Government constituted another team under the leadership of Professor Umaru Shehu, a respected Professor of Medicine, to evaluate the OPV vaccine.

In our search for laboratories suitable for confirmatory and quantitative tests, we faced many obstacles because it was an unusual kind of test and all our efforts to enlist the support of other laboratories at IAEA and RIVM Bureau for International Cooperation in the Netherlands failed.

On November 21, 2003, we sent two NAFDAC officials to South Africa's Van Drimmelen and Lancet Laboratories, both in Johannesburg. Lancet Laboratories declined to participate, but Van Drimmelen accepted. Determination of low levels of impurities in the parts per billion ranges involves the use of sophisticated technology. We therefore inspected Van Drimmelen laboratory facilities to ensure that they had this capacity. Thereafter, the six samples we took there were tested for HIV, B-HCG, Testosterone, Progesterone and 17B-Oestradiol, using the ELISA method. In evaluating impurities in vaccines and biologicals, ELISA is the preferred method because of its specificity, sensitivity and accuracy. The colour change, as a result of the enzymatic activities, is quantified spectrophotometrically. From South Africa, the NAFDAC team proceeded to India to meet Dr. Ramakant Gudal, who had arranged some laboratories for our use. They visited the Drug Control Laboratory of Food and Drug Administration, Mumbai, India, on November 27, 2003. They agreed, on an informal basis, to screen the OPVs for steroidal hormones (Progesterone, 17B-Oestradiol and Testosterone) using High Performance Thin Layer Chromatography (HPTLC) and to quantify the contaminants using a densitometer. This method is as sophisticated as the ELISA method used in South Africa. The vaccine samples were deposited the same day and

the results were expected the next day. By the time the team went back for the results, the vaccines were returned to them because the laboratory officials feared legal challenges.

On November 27, 2003, the team visited the National AIDS Research Institute (NARI), Pune, India. The Institute acknowledged the receipt of eight samples of OPVs to test for HIV, isolate and culture the virus if present and assess the potential of the vaccine as a medium for HIV growth. It is noteworthy that tests for HIV and hormones were requested, but since the laboratory did not have the facilities to analyse the hormones, they decided to go into a detailed evaluation for HIV, their area of specialty. In the end, they said it would take three weeks to give us the results. Efforts to find other suitable laboratories in India were unsuccessful.

After our investigations, I wrote to President Olusegun Obasanjo, making the following observations and recommendations:

*From NAFDAC's investigative analyses, the HIV test was negative in all six vaccine lots tested. Hormones found present are summarised in the table below.

Table 5: Results of Test on Hormone Levels in OPV

Hormone	Range Detected	Mean (SD)
B-HCG	0.9 – 1.7 mIU/ml	1.3 (± 0.30)
Testosterone	0.16 – 2.06 nmol/L	0.76 (± 0.92)
Progesterone	0.1 – 0.3 nmol/L	0.15 (± 0.05)
17B-Oestradiol	114 – 120 pmol/L	115.5 (± 2.35)

* A quantitative analysis by an independent laboratory abroad showed that the quantity of the hormones contained in the OPV could never be harmful to children because they were very much below the normal body levels.

* The analysis was not only carried out using vaccines from NPI, but also on samples received from a neutral party who also imported the drugs, and the results from both sources were similar.

This proved conclusively that there was no discriminatory conspiracy to produce and supply low quality or contaminated vaccines to Nigeria.

The Joint Federal Government / Jamma'atu Nasril Islam (FGN/JNI) All - Inclusive Final Verification Committee on the Safety of Oral Polio Vaccines (OPV)

Following the controversy over the safety of Oral Polio Vaccines, the Federal Government of Nigeria and Jamma'atu Nasril Islam (FGN/JNI) constituted a committee of stakeholders to conduct joint and all-inclusive verification tests in South Africa, Indonesia and India. The Committee comprised:

1. HRH, Alhaji Kyari Ibn Umar El-Kanemi, Leader of the delegation.
2. Prof. Emeritus Umaru Shehu, CFR, Deputy Leader of the delegation.
3. HRH, Alhaji Attahiru Muhammed Ahmed, CON Emir of Zamfara.
4. HRH, Malam Awwal Ibrahim, Emir of Suleja.
5. HRH, Alhaji (Dr) Haliru Yahaya, Emir of Shonga.
6. Alhaji Hassan Ahmed Danbaba, Sultan of Sokoto's Representative.
7. Justice Abdulkadir Orire CON, Secretary General JNI.
8. Dr Basheer I. Mohammed, JNI, Maxillo-facial surgeon.
9. Dr Lawal Bichi, Kano State Pharmacologist.
10. Mohammed M. Hassan, Kano State Laboratory Scientist.
11. Hajia Summaye Hamza, Science Educationist.
12. Alhaji Sani Salauwa, Public Health Epidemiologist.
13. Dr. Haruna Kaita, Pharmacist.
14. Abdulhamid Babatunde, Committee Secretary, Media Consultant.
15. Prof. H.A.B. Coker, FGN, Professor of Pharmacy.
16. Prof. O. Abudu, FGN, Gynaecologist.
17. Dr J.A.F. Momoh, FGN, Chemical Pathologist.
18. Dr Abdulmumuni Rafindadi, FGN, Pathologist.
19. Mrs Titilope Owolabi, FGN (NAFDAC), Pharmacist.
20. Mrs Moji Makanjuola, NTA/FGN, Health Correspondent.

At its first meeting held on February 7, 2004, in the office of the then Minister of Health, Professor Eytayo Lambo, the following resolutions were adopted by the Committee.

* **Resolution 1: Samples of OPV to be taken include:**

- (a) Samples tested earlier by the Kano State Committee on OPV.
- (b) Samples from NPI's strategic store of recently delivered OPV stock.
- (c) Samples from Sokoto, Zamfara and Kaduna States as collated by Dr Haruna Kaita on behalf of JNI.
- (d) Samples from NAFDAC quarantine stock corresponding to a, b and c.

* **Resolution 2: Methodology**

Methodology to be adopted to include Gas Chromatography/Mass Spectrometry (GC/MS), Radio-Immuno Assay (RIA) and High Performance Liquid Chromatography (HPLC), or as advised and agreed upon with the laboratories.

* **Resolution 3: Protocol**

Protocol to be adopted to be arranged with specific laboratories based on their type of equipment, equipment sensitivity and detection limits. The equipment shall be expected to be suitable for detection of suspected anti-fertility hormones and other possible contaminants.

* **Resolution 4**

Baseline validation of protocols shall be as per World Health Organization (WHO) guidelines and subject to sharing of information between analysts in the specific laboratories and the scientists on the committee.

* **Resolution 5**

Countries of tests shall be South Africa, Indonesia and India. The proposed list of laboratories prepared by the Federal Ministry of Health/NPI shall not be exclusive: the Committee at its discretion in each designated country may add other laboratories.

* **Resolution 6**

Test results shall be interpreted by a combined team of stakeholders and the laboratory scientists involved in each test, in each laboratory and in each country.

* **Resolution 7**

The guideline on operations document shall be finally processed on completion of all tests.

* **Resolution 8**

The Committee shall conclude the exercise within the time limits set, but there may be time extension, if necessary.

The Committee left Nigeria on February 8, 2004, for South Africa, Indonesia and India and returned on February 20, 2004. Samples of OPV taken for verification were as agreed in Resolution 1.

Although the WHO has no standard protocol for analysing OPV for steroids, it considers the following as the most relevant methodologies for such analysis in this order of preference: GC/MS, HPTLC, RIA. The methodologies adopted by the Committee for the verification tests were the GC/MS in the University of Pretoria, South Africa, while HPTLC and GC/MS were adopted for the tests conducted at the Shriram Institute for Industrial Research, New Delhi, India. In Indonesia, no tests were conducted because Biopharma Institute, Bandung, the vaccine manufacturing firm, had no experience in the required tests and needed to assemble a team of experts to consider the possibility of running the tests in the first place. However, there was an understanding that the committee might send samples for testing, at a later date, if Indonesia's Regulatory Authorities so approved.

Protocols were discussed in Pretoria, South Africa and New Delhi, India. Discussions covered the types of equipment to be used, equipment sensitivity and detection limits and the suitability of the equipment for detection of suspected anti-fertility hormones and other possible contaminants. Baseline validation of the protocols was also achieved in each test case.

Prior to, and after each test procedure, there were interactive sessions between various laboratory experts in the countries visited and members of the Committee. These sessions clarified uncertainties.

The first test using the GC/MS was conducted at the University of Pretoria, Chemical Pathology Department, with six members of the committee remaining with the laboratory scientists to observe the procedure. A total of 12 batches were submitted for testing. The laboratory, as contained in the analytical report, submitted analysis for Oestradiol and

Progesterone and details of the experimental procedure. The test results were presented to all the members of the committee by the Director of the Laboratory, Dr Tim Laurens, assisted by two expert associates, Messrs J.P. de Coning of the Nuclear Energy Corporation of South Africa and J.H. Spies of the University of Pretoria.

The committee received the HPTLC and GC/MS results for all the 15 samples submitted earlier to the Shriram Institute for Industrial Research in India. Before the departure of the committee from India, the results of the HPTLC were discussed with the Director of the Institute, Dr R.K. Khandal and his colleagues.

However, the GC/MS results from India were to be sent to the committee in Nigeria on February 29, 2004. This was because the validation of this procedure required more time, since this was the first time such a test was being requested and conducted at the research institute.

At a meeting of the committee with the then President, Chief Olusegun Obasanjo, and the Minister of Health, Professor Eytayo Lambo, on February 24, 2004, it was agreed that the committee should not issue an interim report, but should issue only a final report when all the results had been received, interpreted and agreed upon by all representatives of stakeholders in the committee. This was to avoid fueling the controversy. However, the leader of the delegation was allowed to give a press briefing.

The interpretation of the GC/MS results from Pretoria, South Africa and the HPTLC results from New Delhi, India was done by a combined team of stakeholders in the committee and the laboratory scientists involved in the tests.

Using the same GC/MS technique, one laboratory showed no presence of Progesterone in any sample, while the other showed presence in seven samples; one laboratory showed presence of Oestradiol in six samples, while the other laboratory showed its presence in three samples. However, only two samples showed results consistently above the minimum quantifiable limit in both laboratories using GC/MS. The HPTLC tests carried out in India showed no presence of Oestradiol or Progesterone in any of the samples. The results obtained within and between laboratories were inconsistent, not correlated and not reproducible.

Although the results showed no correlation, the highest values obtained in the results were trace levels. Trace levels are not clinically significant. It should be noted, however, that prior to the Nigerian controversy, there was no evidence of testing OPV for steroids by the WHO, manufacturing companies and regulatory agencies.

The conclusion of the Joint FGN/JNI All-Inclusive Committee on the safety of OPV was exactly the same as that of NAFDAC: the Agency had stated authoritatively that OPV was safe for human use and that test results showed that the contested substances were present at such low levels that they could not cause harm, kill or cause infertility. Possible explanations for such low levels may be process/product-related, in view of the fact that calf blood (serum) is used to facilitate the growth of the polio virus.

FOOD CASES

The Indomie Noodles Scare

De-United Food Industries Limited, a leading food company, manufactures Indomie Instant Noodles in their factories in Otta, Ogun State and Port Harcourt, Rivers State. The factories have installed capacity of 500,000 packs and 468,000 packs per day respectively, with the Otta factory running at 100 per cent installed capacity and the Port Harcourt factory running at 50 per cent. Indomie Instant Noodles was first registered in 1997 and so far, 11 flavours have been duly registered by NAFDAC.

De-United factories' GMP inspections were last carried out on September 25, 2003, for the Otta factory and on April 26, 2004, for the Port Harcourt factory. The results of the GMP inspections for both factories were satisfactory.

In addition to the GMP inspections, the imported seasonings were also sampled at the ports of entry and tested for safety and quality. They were released to the manufacturer only when they were found to be satisfactory. From 2001 to the time of the noodle crisis, we had analysed 74 batches of seasonings used for the noodles. In sampling and testing imported seasonings, we routinely carried out physico-chemical (moisture content, ash content), microbiological and heavy metal contamination analysis. We tested for the level of Monosodium glutamate (MSG), to ensure that it did not exceed acceptable limits in food products. Our records showed that all tested batches of Indomie seasoning passed these routine tests.

From May 11, 2004, we received several telephone calls, text messages and a complaint from the then Commissioner of Health for Lagos State, Dr Leke Pitan, alleging that some people became sick after eating Indomie Instant Noodles. The Health Commissioner instructed

all Lagos State hospitals to report all cases of food poisoning to his office. The following actions were taken:

1. May 11, 2004 – NAFDAC invited the management of De-United Food Industries Limited to discuss the reports. On the same day, our inspectors went to inspect the factories even though their GMP certificates were still valid. In-process samples and finished products were collected for analysis. The Quality Control managers were also interviewed. We also issued an alert notice requesting the public to report any incidence of food poisoning or death linked to the consumption of Indomie noodles.
2. May 12, 2004 – Further inspections were carried out on the factories.
3. May 12, 2004 – The factories were shut down pending conclusion of our investigations. We had to do this because of reports that many people had been hospitalised and someone was even claimed to have died following consumption of Indomie Instant Noodles.
4. May 13, 2004 – Indomie noodles stored at two major distribution warehouses in Lagos and Port Harcourt were placed on hold.
5. We collected samples of Indomie noodles for analysis from the major distribution warehouses and markets. Samples were also collected from the retail kiosks identified as the places where the families of the complainants, including the family of the person who had died, bought their noodles.
6. All samples collected were sent to our Oshodi laboratory for analysis.

Investigations

1. Administrative Inspection:

We examined areas of possible contamination such as the water system, raw materials and stores, as well as the quality control systems and documentation. In each factory, we collected samples of dough, steamed noodles and finished products from the critical areas of the manufacturing process and sent them to our laboratory for analysis.

2. Interview of Complainants:

We received hundreds of telephone calls and enquiries regarding the Indomie noodles crisis and carried out 17 telephone interviews and six face-to-face interviews. There

were reports of 23 cases of diarrhoea and vomiting from Lagos, Port Harcourt, Akure, Enugu and Abuja. Although there were many death speculations, only one was confirmed. Indomie noodles is very popular with Nigerian children. This was indeed a crisis. Both parents and children waited anxiously for the outcome of our investigations.

3. Visits to Hospitals and Affected Families:

We visited a total of six hospitals in the course of the investigations: four in Lagos, one in Abuja and one in Nsukka. Two cases involved hospitalisation – one in Lagos and one in Abuja. One of the families visited was that of late Mr Oluyemi Moritiwon, the only case of fatality. It was alleged that Oluyemi had bouts of diarrhoea and vomiting after a meal of the chicken-flavoured Indomie Instant Noodles. The family confirmed the incident, but informed our team that the deceased had a prior history of heart problems. We also interviewed Dr Dayo Banjo, their family doctor, who is also in charge of the Telab Clinic, where the deceased was first admitted. According to him, the death might not be directly linked to the noodles and confirmed that the patient had an enlarged heart, which necessitated his referral to Lagos University Teaching Hospital, where he eventually died. At LUTH, Dr David Oke reported that the deceased had a congenital history of breathlessness. We therefore wrote to the Chief Medical Directors of both the Telab Clinic and LUTH, for their professional opinions on the incident. LUTH replied that the medical report would be forwarded as soon as it was available, while the Telab Clinic stated that it was not in a position to establish a direct link between the ingestion of Indomie noodles and the death.

Despite our appeal to the public to report any case of food poisoning or death due to the consumption of Indomie Noodles, we did not receive any concrete information concerning any patient to enable us establish the link between the noodles and the reported food poisonings.

4. Laboratory Findings:

- i. The microbial assessment of the samples analysed was within acceptable limits.
- ii. Chemical contaminants such as heavy metals, cyanide, petroleum and petroleum products' derivatives were not detected.

- iii. Out of the 28 batches tested, three were found to be contaminated with Carbofuran, a very toxic pesticide, at levels above acceptable limits. Laboratory analysis showed that the Carbofuran contamination was from the seasoning and the chilli.
- iv. Toxicological tests: the affected batches tested on laboratory animals revealed that all the animals showed ill health, but recovered after 24 hours.

Carbofuran is a Carbamate pesticide used in agriculture. It has acute toxicity that can cause diarrhoea, vomiting, chest pain, blurred vision, anxiety and general muscular weakness in humans exposed to levels above the maximum allowable contaminant level. The levels of Carbofuran present in the noodle meal might have been responsible for the reported cases of diarrhoea and vomiting. Since the hospitals did not establish a direct relationship between the consumption of these noodles and the deceased, a forensic report from the hospital was necessary to conclusively determine the cause of death. However, we did not get any other report from any of the hospitals, despite all efforts.

NAFDAC's Verdict

Indomie Instant Noodles Chicken Flavour:

Since we had conclusively determined that the three contaminated batches of *Indomie* noodles were produced between March 30 and April 2, 2004, we directed De-United Food Industries Limited to recall all such noodles produced within that period from their warehouses, distributors and retailers for destruction by NAFDAC.

Thereafter, we initiated a nationwide mop-up of the contaminated noodles batches through our state offices. Mindful of the fact that these products were in circulation, we advised the public through print and electronic media to return the contaminated batches to the nearest NAFDAC office.

We appealed to the public to report any adverse effect from the use of any NAFDAC regulated product and to avoid destroying or discarding remnants and packaging of suspected products, for easy tracing and testing. This is of paramount importance, because during the investigations, we were unable to retrieve samples of remnants from most of the victims and their families. We subsequently assured the public that these particular noodles, with the exception of those with manufacturing dates from March 30, 2004 to April 2, 2004, were safe for human consumption. The factories in Otta and Port Harcourt were re-opened on May 20, 2004.

Through the mopping up and recalling exercises, and with the assistance of the public and De-United Food Industries Limited, we recovered about 21,025 cartons of 40 packs each of noodles worth over ₦20 million (US\$174,000). The noodles were destroyed publicly in Lagos on June 18, 2004.

We published public notices in major national newspapers to keep the public well informed, reiterating the relevant results from our investigations, along with our recommendations.

Importation of Bags of Expired Skimmed Milk Powder by Nestle Nigeria Plc

Nestlé Nigeria Plc, the local branch of global conglomerate, Nestle, imported nine forty-foot containers filled with 6300 x 25kg bags of expired skimmed milk powder in January 2001 for production of baby foods. This case occurred three months before my appointment but was brought to my attention by Mrs Chinyere Ukaegbu, a Deputy Director. I immediately ordered a review and proper investigation of the case and instructed that anyone found culpable should be held accountable. The expiry date was altered to read February 2002 instead of the original date of February 2001. When NAFDAC inspectors challenged the company, its employees claimed that it was a labelling error. NAFDAC investigations uncovered more inconsistent expiry dates. Furthermore, the documents Nestle presented for clearing the cargo showed that they had under-declared the quantity of products. Many companies under-declare the quantities of products in their importation manifest in order to avoid paying the full customs duties due. NAFDAC ordered the forfeiture of the expired milk products for destruction. Nestlé filed a lawsuit against the agency, seeking injunctive relief and followed it up with a series of media campaigns. After some meetings between our offices and Nestle, and a letter from our solicitor to the Nigerian police to investigate the case, the company withdrew the case in favour of an out-of-court settlement. NAFDAC eventually destroyed the expired milk imports on December 18, 2001 and in accordance with regulations, the cost of destruction was borne by Nestle.

Revalidation of Expiry Dates on Chocolate Bars by Cadbury (Nigeria) Plc

In March 2002, NAFDAC intelligence indicated that Cadbury (Nigeria) Plc, the local branch of another multinational company revalidated the expiry dates on chocolate bars it produced. An unannounced inspection of the company's warehouse by NAFDAC Enforcement Officers confirmed the allegation. Both the expired and unexpired chocolate bars were stored together, instead of separating the expired stock in quarantined areas.

NAFDAC placed all the expired but revalidated stock on hold while investigations commenced. Laboratory analysis of samples drawn from the stock confirmed that they were degenerating. The Agency filed a suit against Cadbury (Nigeria) Plc at a Federal High Court in Lagos. They admitted their wrongdoing and sought an out-of-court settlement, which was accepted. A fine was imposed as penalty in lieu of dismissing the suit.

Park ‘N’ Shop Supermarket

During routine surveillance by the Establishment Inspection Directorate (EID), expired food products were found in Park ‘N’ Shop supermarket in Lagos. Many other products without batch numbers and expiry dates were also found. On July 23, 2002, another team from the Enforcement Directorate confirmed the reports and the supermarket was sealed off for four days. During this period, substandard and unwholesome products such as Geisha, baby clam, Acetaminophen children’s chewable tablets, Delicious Barbequed Egg Plant, Gurukripa (wheat) 2kg, Gurukripa (white powder) 2kg, yogurt and cottage cheese were removed from the premises for destruction. After meetings with the management of the supermarket, NAFDAC issued a fine in addition to insisting on a management apology for the lapses. It is heartwarming to note that this incident not only made several other supermarkets self-regulate, but also inspired the operators to set up a national association of supermarket operators in Nigeria, with the principal aim of ensuring that members comply with NAFDAC’s regulations. Since the reopening of Park ‘N’ Shop, they have been complying with all of the regulatory agency’s rules and guidelines to the extent that separate shelves have been provided for the about-to-expire products in the supermarket.

The Death of a Family of Five

News of the death of a family of five in Kobi Village, Abuja, the Federal Capital, on the night of August 22, 2006, came as a rude shock to the nation. NAFDAC investigators swung into action immediately, visiting the scene and collecting samples of food and drink from the family’s one-room abode for analysis. The items collected included a bowl of kunu drink (a fermented milk drink), a pot of herbal medicine, a pot of water and some uncooked food items. The test results showed that the kunu contained a rat poison called Otapiapia, which contains Dichlorvos as the active ingredient. It contained 140mg of Dichlorvos per kg as against the 50mg per kg required to kill laboratory rats. It meant that about one-third of the dose of Dichlorvos in the kunu would be more than enough to kill laboratory animals. We informed the public of the outcome of our investigations. We also warned against the

use of *Otapiapia* as rat poison because it is extremely toxic and dangerous to human life, if it accidentally gets in contact with food or drink.

Taste of Soft Drinks Produced by Coca-Cola Nigeria Plc

Millions of Nigerians travel abroad every year and millions more live in the developed countries of Europe and America. It is not surprising therefore, that many people in Nigeria would expect the same quality from the local branch of a trusted multinational company like Coca-Cola as they would get abroad. However, in 2002, there were regular complaints by the public that some Coca-Cola products contained extraneous substances and that the locally produced Coca-Cola, Sprite and Fanta had different tastes from the ones produced in developed countries. There were also complaints that the sugar content was too high. In view of these complaints, NAFDAC wrote a letter to the Nigerian Bottling Company (NBC), the manufacturer of Coca-Cola products in Nigeria on November 22, 2002, detailing the public complaints and requesting the company to submit results of taste tests conducted on Coca Cola products in Nigeria from 1994 to the regulatory Agency (Appendix 18). Afterwards, NBC was invited by NAFDAC to discuss these concerns. They agreed that the sugar content was higher than that used in developed countries, and that it was made that way to suit the local consumer taste. A compliance directive was issued, directing them to reduce the sugar level in the drinks within one year. After one year, NBC brought some bottles of their products to NAFDAC to show that the directives had been complied with.

Adulterated Palm Oil

In Nigeria, the aesthetic value of food is highly prized. Palm oil in its natural state has a red colour. However, on prolonged storage, it undergoes partial discolouration and loss of visual appeal. When some newspapers reported that 30 per cent of palm oil sold in Nigeria owed its intense red colour to colouring agents, NAFDAC instituted an investigation. During the investigation, 30 samples of palm oil taken from Imo, Lagos, Oyo, Osun and Plateau States and the Federal Capital Territory, Abuja, were found to contain Annatto dye, a red dye that is a permitted food colourant. Annatto dye has been reported to cause nettle rash, a minor health hazard. A greater health hazard however, was Azo dye, found in a sample of palm oil from Osu, in Osun State. Azo dye is a proven carcinogen. We learnt that the perpetrators of this crime mixed water, palm oil, potash and Azo dye to obtain larger volumes of adulterated palm oil, which also has a very attractive red colour. Palm oil traders educated our staff on how to differentiate between Azo dye-adulterated palm oil and non-adulterated palm oil.

To help protect the public, we developed a quick means of identifying adulterated oil. When the adulterated palm oil is vigorously stirred in a transparent glass and allowed to settle for about 30 minutes, the sample with Azo dye separates into two distinct layers – a wine-red top layer and a thick yellowish lower layer with whitish particles. The unadulterated sample settles uniformly with no demarcation or particles. To stop the adulteration, manufacturers were commissioned to produce Azo dye spot-testing kits for use by NAFDAC field officers. To enlighten the public, we included information on the hazards of Azo dye and palm oil adulteration in our grassroots mobilisation campaign.

Report from British High Commission Alleging Exportation of Contaminated Palm Oil from Nigeria to the UK

In January 2005, I received a letter from Martin Shearman, the acting British High Commissioner to Nigeria, requesting assistance with a problem raised by the United Kingdom Food Standards Agency (FSA). The letter also contained notification 2005.009, published on the Rapid Alert System for Food and Feed (RASFF) website, titled Unauthorized colour Sudan IV in palm oil from Nigeria via United Kingdom and via the Netherlands. The FSA was concerned that unrefined palm oil contaminated with the Sudan IV dye was allegedly being imported into the UK from Nigeria. Mr Shearman requested NAFDAC's assistance in identifying the producer(s) of the palm oil in order to determine the composition of the product and the source of the Sudan IV dye.

Sudan IV, also known as Scarlet Red, is one of the Sudan series I–IV dyes used for colouring solvents, oils, waxes, petrol, shoe and floor polishes. Some manufacturers of palm oil illegally add it to brighten the oil, making the palm oil more visually appealing to consumers. Sudan IV is considered a genotoxic carcinogen and under the Nigerian Food Regulations 1995 is not permitted in foods for any purpose. As the allegation bordered on health, security and our national integrity, we did not hesitate in investigating the issues. After a thorough investigation, we found that the Sudan IV contaminated oil was not exported from Nigeria. The United Kingdom FSA, on whose behalf the Acting High Commissioner was inquiring, had put out notices on its website to the effect that Kokwe Farms Limited of Accra, Ghana, manufactured the palm oil. The products were imported into the UK by Jumbo UK Limited, United Kingdom. Jumbo UK Limited bottled the oil for its own brand, Zomi Palm Oil and as Tropical Sun brand for Wanis Limited, London. The two brands were then sold to the public.

I communicated our findings to Mr Shearman. The indications were that he had not investigated this case thoroughly before indicting Nigeria. Otherwise, he would have found that the country of origin of the oil was Ghana and not Nigeria, and therefore any adulteration must have taken place in either Ghana or the United Kingdom. Recognising the implications of this allegation to our national integrity and reputation, as well as its negative impact on Nigerian export trade, I wrote letters to Mr Chukwuemeka Chikelu, Minister of Information and National Orientation at the time; Prof. Eytayo Lambo, Minister of Health; Chief Ufot Ekaete, Secretary to the Government of the Federation, and General Abdullahi Mohammed, Chief of Staff to the President, to inform them of the matter.

On February 11, 2005, I received a letter from a delegation of the European Commission to Nigeria on their previous notification on Unauthorized colour Sudan IV in palm oil from Nigeria via United Kingdom and via the Netherlands. Marc Friedrich, the Chargé d’Affaires wrote:

“Additional information has shown that the true origin of the product was Ghana. I would therefore like you to disregard my original letter. The Director General, Health and Consumer Protection will also publish a corrigendum in the weekly overview on the Rapid Alert System for Food and Feed (RASFF) web site ... Please accept my sincere apologies for any inconveniences this error may have caused.”

The Use of Expired Food Items at the Nikon Hilton Hotel, Abuja

On Friday, September 24, 2004, we received a complaint at NAFDAC Headquarters, Abuja, alleging that expired food items were being served at the Nikon Hilton Hotel, now the Transcorp Hilton Hotel. The complainant, who was an employee of the hotel, submitted samples of expired Rosenburg Danish Blue Cheese, which he said was being used at the hotel. We also received a letter from the Secretary to the Government of the Federation, Chief Joseph Ufot Ekaette, requesting NAFDAC to investigate the matter. Apparently, the complainant had also reported the matter to Chief Ekaette. On the same day, we dispatched a team to inspect the food and beverage department of the Nikon Hilton Hotel. In all, 850 pieces of 100g packs of Rosenburg Danish Blue Cheese with no date of manufacture, no batch number and with an expiry date of 11/09/04 were found in the hotel’s old butchery that was being renovated. Our team seized the expired products and we issued an administrative summons to the Food and Beverage Manager asking him to report to our office on Monday September 27, 2004.

He arrived at our office that Monday accompanied by two other hotel officials, the Chief Chef and the Chief Security Officer. They all claimed that they did not know that the cheese had expired. They explained that the hotel's Controller had written to NAFDAC the same day to inform us about the expired products. Investigations showed that the letter was sent to the office of the Director General at the same time that NAFDAC officials were inspecting the hotel. The hotel officials also claimed that they did not know they were required to turn in expired items to NAFDAC for destruction. This was a surprise because our officials had visited the hotel in the past to educate them on proper handling and disposal of such products. After the meeting, we decided to re-inspect the food and beverage department during which we found several other expired and unwholesome products. The unwholesome food products we found included those listed in Table 6.

The General Manager was unavailable for a meeting with the Agency and was represented by the Business Development Manager. The hotel officials expressed regret and a readiness to comply with all our directives. They were instructed to submit the purchasing invoices for the substandard and expired food items, so that the sources and persons responsible for changing the expiry dates could be traced. They were also asked to sign a letter of forfeiture for the expired products. Compliance directives were issued to the effect that the Nikon Hilton Hotel in Abuja would:

- Observe proper stock rotation and regularly set apart products that are about to expire. Such shall be kept on separate shelves or sections that must be adequately labelled.
- Purchase and use only food products that are registered by NAFDAC. Such products must have all mandatory labelling information:- Manufacture Date, Expiry Date, Batch Number, NAFDAC Registration Number, Manufacturer's Name and Complete Address and labels in English language.
- Write a statement of undertaking to NAFDAC, that the hotel will not stock or use expired or unwholesome food products again.
- Pay fines for the following offences: use of expired food items, stocking of food products with altered expiry dates, use of improperly labelled products, possession of products labelled in foreign languages without English translation and use of fake and substandard food products.

The hotel management responded in writing and stated that;

- They had implemented additional measures and procedures to improve procurement standards, storage and use of food and beverages in the kitchen. Items with below 30 days remaining shelf life were automatically released for immediate use.
- Foreign food and beverage purchases would be done with all necessary approvals from NAFDAC.
- They would not stock expired and substandard food products and would comply with agreed standard procedures.
- The fines would be paid, and they paid.

Table 6: Expired and Unwholesome Food Products found in Nicon Hilton

Name of Product	Manufacture Date	Expiry Date	Batch No.	Quantity
Moutarde de Dijon	Not Stated	real 25/12/01 fake 22/06/05	Not stated	352 pcs x 370g
Ducros	Not Stated	Not Stated	Not Stated	236 pcs x 500g 112 pcs x 1kg
Ducros Leaf	Not Stated	Not Stated	Not Stated	20 pcs x 250g
Tumeric Powder	Not Stated	Not Stated	Not Stated	1 piece x 100g
Glucose Baker	Not Stated	Not Stated	Not Stated	90 pcs x 200g
Musesli Luxury	Not Stated	19/10/04	Not Stated	1 piece x 2kg
Spice Origin	Not Stated	Not Stated	Not Stated	42 pcs x 28g

Closure of Dangote Flour Mills in Kano

In line with the provisions of Food Fortification with Vitamin A Regulation 2005, NAFDAC enforces the fortification of all flour, sugar, vegetable oil and related products manufactured, sold and consumed in Nigeria. This regulation provides that all such products must be

fortified with 30,000IU of Vitamin A per kg. Vitamin A fortified products are identified with the Vitamin A logo on the product package, which comprises an eye with a big letter A in the centre.

In order to ensure that all manufacturers and importers comply with this regulation, we routinely monitor and inspect production facilities of the referenced products, and constantly sample and test the imported ones.

During one such routine visits to the Dangote flour mills in Kano, which involved sample collection and laboratory testing, our staff discovered that Danvita Wheat Semolina, which did not contain any Vitamin A, was labeled with the Vitamin A logo. We viewed this as an act of sabotage against public health because of the serious health problems associated with Vitamin A Deficiency (VAD). Vitamin A is a micronutrient vital for the proper functioning and development of the body. It is essential for the maintenance of eye vision and the body tissues and immune system. Its deficiency causes xerophthalmia (night blindness), dry scaly skin, and reduces immunity, thereby predisposing victims to infections. It is worthy of note that in the mid 1990s in sub-Saharan Africa, 25 per cent of deaths of children under 5 years of age was attributed to VAD. Consequently, the factory was closed down and the management was directed to recall the unfortified Semolina product, and start fortification. In two letters to us, dated May 18, and 20, 2007, the company promised to stop the production of Danvita without Vitamin A, and recall those already in the market. They also paid a fine before the company was re-opened.

Cosmetics and Combined Products

The Ojo Military Cantonment (Lagos) Mammy Market Counterfeiters

The long years of military rule in Nigeria spawned a steady growth of sprawling settlements within military barracks. Inside these settlements, there are markets popularly called mammy markets. In these mammy markets, production, stocking and sale of a wide range of products, including regulated products, were carried out with complete disregard for regulatory laws. These settlements were impenetrable because of the close links between the operators and the military. Their proximity to, and association with military formations made these mammy markets safe havens for the massive faking and counterfeiting of many regulated products. Surveillance visits by our officers showed frightening levels of fake and substandard regulated products ranging from drugs, food and cosmetics, to medical devices, detergents and packaged water. Companies whose products were faked were helpless, as the “products” made in

these settlements were freely distributed with the knowledge of some military officers-in-charge. Some of the officers were not ready to cooperate with NAFDAC to rid the cantonments of these spurious products. It appeared impossible for any meaningful regulatory function to be performed inside these settlements, even when the evidence of violations and the attendant health hazards were overwhelming.

However, in November 2002, NAFDAC officers, supported by officers of the military intelligence and the military police, stormed the notorious Ojo Military Cantonment mammy market. The operation, which lasted for six days, involved shop-to-shop and factory-to-factory inspections, covering 86 shops and “factories”. A wide range of fake and adulterated products were impounded. We seized non-sterile water for injection, assorted brands of insecticides such as Baygon, Mobil, Shelltox, Rambo and Raid; alcoholic drinks popularly called “hot drinks”, like Dry Gin, Whisky and Rum; fruit juices such as Five Alive and Just Juice; and non-alcoholic beverages such as First Lady and Eva. Also seized were various soap brands such as Joy and Lux soaps, beverages such as Bournvita, Ovaltine and Milo; ice creams and yogurts, including Fan Ice and Yogo, were also seized. Cosmetic products, such as TCB hair products, Sporting Wave and Sinclair creams; and sanitary towels such as Comfit were confiscated. The seized products, with a street value of over ₦500 million (US\$4.35 million), were destroyed in March 2003.

NAFDAC Seizes Tubes of Fake Top-Gel MCA

NAFDAC officers at one of the border posts in Lagos confiscated a consignment of fake Top-Gel MCA (Fluocinonide 0.025g/100g), a cream for skin conditions, valued at ₦25 million (US\$217,391), imported by Winmax, a company based in Lagos. This seizure was made possible because of a timely tip-off from a member of the public. GSK had discovered that a Chinese factory was producing fake Dermovate and Top-Gel MCA (GSK products) for export to African markets. The fake Top-Gel MCA was shipped to Nigeria via the port of Cotonou, Republic of Benin. The details of the container were provided by GSK to a NAFDAC surveillance unit and included the ship’s name (Ocean Hope), the place of delivery (Cotonou, West Africa) and the consignee (Winmax, Lagos). This container contained a large quantity of counterfeit Top-Gel, labelled as a product of MCA (Medical & Chemical Agency SPA S. Vittore Olana, Milan). The Top-Gel bore a fake NAFDAC registration number on the packet. In addition to notifying NAFDAC, GSK also notified MCA, makers of genuine Top-Gel MCA. Based on this information we intensified our surveillance activity at the border posts of Idiroko and Seme.

Nichben Limited, the Nigerian agent for MCA, later informed us that the Top-Gel consignment had arrived Cotonou and was being transferred to a truck heading to the Igolo–Idiroko border. Local informants alerted NAFDAC inspectors at Idiroko border that the goods had been transferred again from the conveying truck to another heading to Lagos. One of the surveillance officers used his car to obstruct the truck at the border post and instructed the driver to unload its contents for examination. On examination, 257 cartons of 64 packs x 10 x 30g tubes and 52 packs of 10 30g tubes of fake Top-Gel were found. Information details on the pack were as follows:-

Batch Number: 183

Manufacturing Date: 03/09

Expiry Date: Not indicated

NAFDAC Reg. No.: 04–0406

Manufacturer name and address: MCA Medical & Chemical Agency SPA S., Vittore, Olana (Milan), Via Panini, 1/3 Italy

MCA Medical & Chemical Agency SPA, Italy, the company that manufactures Top-Gel MCA registered by NAFDAC confirmed that they have no manufacturing facility in China and have never sold their products to Winmax, Lagos.

Top-Gel MCA contains Fluocinonide, a topical steroid used to treat severe skin conditions such as actinic and seborrhoic dermatitis, psoriasis, skin lesions, eczema, burns and herpes. Due to the active presence of NAFDAC at the seaports, smugglers divert their illicit consignments to the Benin Republic, which shares land border with Nigeria.

Importation of 104 x 25kg Kegs of Menthol Crystals by PZ Industries Nigeria Limited.

On April 9, 2002, PZ Industries Nigeria Limited imported 104 x 25kg kegs of menthol crystals. The consignment had red ‘reject’ labels attached to them. A ‘reject’ label in pharmaceutical terms mean that the product is not approved for use due to non-conformity with standards. We placed the consignment on ‘hold’ in PZ’s warehouse and issued them a query. While awaiting PZ’s response, samples were drawn and sent to our laboratory for analysis. In PZ’s response, their explanations were not satisfactory. We therefore prosecuted

PZ for this offence. With the overwhelming evidence against the company, they pleaded to settle out of court. We agreed, only after they paid a stipulated fine.

OTHER CASES

Closure of Unilever Nigeria Plc

We received consumer complaints in February 2005 that Close-Up toothpaste, a Unilever product with batch numbers BN3, BN4 and BN6, was suspected to be of substandard quality. The reasons for the complaints were the off-taste and lack of foaming properties of the product. Other complaints included a burning sensation on the gums and coughing after use, especially by children.

NAFDAC dispatched a team of inspectors to the Unilever's depot in Ibadan on February 18, 2005 to retrieve samples for laboratory analysis. Preliminary laboratory test results raised a red flag. We therefore, placed all the products in the depot on hold pending the conclusion of our investigations. NAFDAC inspectors were informed at the Ibadan depot that Unilever was already recalling the affected batches of Close-Up toothpaste from circulation.

On February 22, 2005, NAFDAC inspectors again visited the factory in Lagos to assess the effectiveness of the ongoing recall action and perform a GMP assessment of the plant. During the visit, our inspectors were refused access to relevant documents and samples of the recalled batches. These samples were needed for analysis. Due to their uncooperative attitude, we sent them a letter of caution on February 23, 2005. Realising the implication of this act of obstruction to NAFDAC statutory regulatory duties, they allowed our officers to collect the samples and all relevant documents. NAFDAC officers in the states nationwide were also instructed to carry out surveillance on the affected batches of Close-Up toothpaste and supervise their withdrawal from circulation. We carried out another inspection on February 23, 2005 for a GMP appraisal of the factory in Lagos, during which we observed the following:

- i. Quality Control parameters for laboratory analysis of the toothpaste were not comprehensive enough to check all possible mistakes during production. Tests for homogeneity, foaming and fluoride content were lacking. There was no equipment for fluoride analysis in the factory. There was also no documentary evidence of fluoride analysis ever being performed anywhere at any time by the factory.

- ii. The company had changed the formulation of Close-Up toothpaste without notice to NAFDAC.
- iii. Documentation of processes was unsatisfactory.

The GMP was deficient and this was communicated to Unilever through compliance directives. Samples of the recalled batches found in the factory were sent to the NAFDAC laboratory for analysis. In addition, five samples were drawn by our Ibadan office from the Unilever Depot in Ibadan and submitted for laboratory analysis. It is noteworthy that those five samples from Ibadan had no batch numbers. Without batch numbers, there could not be any effective product recall.

With the laboratory results pending, company officials visited NAFDAC's Lagos office on February 24, 2005, to apologise. They tried unsuccessfully to explain why they changed the formulation of Close-Up toothpaste. Their poor GMP was discussed and they promised to rectify all deficiencies. Out of the ten samples that were analysed two had discrepancies in batch numbering; the batch numbers on the tubes were different from the batch numbers on the packets. Four batches had low fluoride content.

On March 31, 2005, we carried out a follow-up inspection of Unilever facilities, to assess their level of compliance with the directives we issued in February 2005. All the directives had been executed with the exception of providing equipment for fluoride analysis. Unilever officials stated that the equipment had already been ordered.

Further complaints from consumers about Close-Up toothpaste necessitated another round of inspections. On May 10, 2005, during an inspection, we drew samples from 12 batches produced in the four weeks preceding the inspection. Analysis of these samples showed that in nine of the samples, the batch numbers on the tubes of toothpaste were completely different from those on the packet. Furthermore, four of the samples had illegible expiry dates and one had no expiry date at all. These problems had persisted for about three months and consumer complaints came in from many more parts of Nigeria. We therefore shut down Unilever's factory on May 12, 2005 and held a meeting with the company to review the situation.

On May 13, 2005, we presented the following inadequacies to the company's representatives:

1. Low fluoride content in one of the recently collected samples.

2. Conflicting batch numbers on nine of the tubes and packages. We informed Unilever that these discrepancies were included in the compliance directive issued to them a month earlier.
3. Unilever had changed product formulation without notifying NAFDAC.
4. Unilever had changed their source of raw materials without notice to NAFDAC. Significant changes of formulation or sources of raw materials without notice to NAFDAC could result in the revocation of the Certificate of Registration of a product.

The company representatives confirmed that they had changed the source of their raw materials from the United Kingdom to India.

It is important to emphasise at this point that product faking was unlikely in this Unilever Close-Up toothpaste saga because our inspectors collected all the samples analysed directly from Unilever's Lagos factory and Ibadan depot. We therefore resolved that Unilever must fully comply with the following conditions before production of their Close-Up toothpaste could be resumed in Nigeria:

1. Unilever Nigeria Plc should install equipment for laboratory analysis of fluoride to determine the fluoride content of their Close-up toothpaste.
2. Unilever should provide detailed reports of analysis of Close-Up toothpaste for the past one year.
3. Unilever should implement all the compliance directives earlier issued to it.
4. On satisfactory correction of all lapses, test-run production would be carried out and samples drawn for analysis. If reports of analysis were satisfactory, the factory would be re-opened for commercial production.
5. After re-opening the Close-Up plant, the GMP and quality of toothpaste would be appraised quarterly.

Follow-Up Actions after the Closure of Unilever Close-Up toothpaste Plant

In a letter dated May 18, 2005, Unilever notified the Agency that it had acquired fluoride-testing equipment and had complied with the other directives. They requested permission to re-open the factory in order to install the fluoride equipment. Permission was given and the plant was re-opened on May 20, 2005. Three days later, Unilever invited us for GMP re-

appraisal. The inspection took place on the same day, during which a test-run was done. Sample products from the test-run were sent for laboratory analysis. The result released on May 25, 2005 confirmed that the product complied with standard parameters. Unilever's Close-Up plant was finally re-opened on May 26, 2005.

Faking Of NAFDAC Registration Certificates or Clearance Stamps for Clearing Fake Regulated Products

We had several seizures prompted by forgery or faking of NAFDAC registration certificate or NAFDAC clearance stamps. Two examples of such cases are:

Seizure of Container of Counterfeit Medicines at Apapa Port, Lagos

In July, 2008, a 20ft container of counterfeit medicines disguised as 2mg Maxcure Loperamide capsules with false labels and bearing the body mark CAQXU 2816358 was imported from India by Malven Medics International Limited. The container was cleared using forged NAFDAC stamps and documents. An Indian and his Nigerian clearing agent had approached NAFDAC officers at the port to offer them bribe to avoid NAFDAC examination of the container before removal from the port. The officers refused the bribe and seized the container.

Clearance of Unregistered Mio Pasta Chocolate

In August 2008, Mr Okechukwu Ilechukwu and his accomplices, Messrs Emeka Oli and Lucky Nwanyelugo, were arrested for faking a NAFDAC Registration Certificate, in an attempt to clear a 20ft container of unregistered Mio Pasta Chocolate from the port. The clearing agent, Mr Emeka Oli, presented this fake document to the Agency in order to obtain a NAFDAC clearance stamp required for clearing the consignment. The officer in charge noted some anomalies in the presented NAFDAC Registration Certificate and decided to seek a second opinion from her superior officer. Suspecting that he had been discovered, Mr. Emeka Oli abandoned the documents and fled. The matter was handed over to NAFDAC's Enforcement Directorate.

A team of Enforcement Officers went after the perpetrators involved in this act including the importers and clearing agents. After several attempts, which included unannounced visits to his residence and the sealing off of his shop, the importer was finally arrested. Mr Emeka Oli confessed that he contracted the clearing agent Guns & Riches Nigeria Ltd. to clear his goods from the ports with forged documents.

Sting Operation at Ekene Dili Chukwu Motor Park

Following a series of surveillance reports about the thriving business of faking, re-labelling and distribution of drugs at Ekene Dili Chukwu Motor Park, adjacent to the popular Onitsha Drug Market, NAFDAC officials carried out a 'sting operation' at the park in October 2003. The premises turned out to be a base for the repackaging and re-labelling of counterfeit and substandard drugs, either imported or locally manufactured. The Park, which consists of shops and warehouses, was also used as a transit point for the distribution of spurious products to other parts of Nigeria and to the West African sub-region.

One remarkable outcome of the operation was the discovery of novel concealment methods these modern agents of mass murder deployed in importing and transporting fake products within Nigeria and the sub-region. Ethical and Over the Counter (OTC) drugs were packed in sealed containers of popular food or non-regulated products, to deceive inspectors and security agents at the ports of entry, in transit and in the warehouses. For example, we found packets of several ethical and OTC drugs concealed in cartons of the popular Peak Milk and Indomie noodles, deceptively labelled as if they contained only these products. A NAFDAC investigation revealed that the drugs disguised as milk and noodles were imported from China. The products were sent to our laboratories for analysis. The substandard ones were seized and destroyed publicly. Apart from alerting Customs and the security agencies of these new methods of concealment, our officers have become more thorough in our screening procedures.

Closure of Chemical Warehouse for Changing Expiry Date of Agrochemical

On February 28, 2008, a concerned citizen alerted us that a company with Head Office in Victoria Island, Lagos, was engaged in the unlawful changing of the expiry dates on their products at their warehouse in Lagos. Our officers wasted no time getting to the warehouse where they apprehended the employees in the fraudulent act of expiry date alterations on one of their product, a form of Endosulfan, an insecticide used mainly by cocoa and cotton farmers. The chemical, which was manufactured in April 2006, with an expiry date of April 2008, was being re-labelled with a manufacture date of January 2008 and an expiry date of January 2010. A total of 1,057 cartons of the chemical were seized from the warehouse. Of these, 528 cartons, each containing a one-litre plastic bottle of the product, had already been re-labelled; 391 cartons, each containing twelve one-litre bottles of the product were about to be re-labelled; and 138 cartons contained products with the old labels already

removed, waiting to be re-labelled. The warehouse was shut down and referred to the Enforcement Directorate for appropriate sanction.

Sand Imported in Containers but Labelled as Instant Powdered Milk

On December 9, 2003, Glopex Trading (Nigeria) Limited of 11A Burma/Commercial Road, Apapa Lagos, obtained NAFDAC's first stamp for "Physical Examination" for a consignment of 2 x 40 foot containers, manifested to contain Glorie instant powdered milk in 25kg bags and imported from Argentina aboard MV Luna Maersk. Each container was valued at ₦7 million (US\$60,870).

A joint examination conducted at the ports on December 17, 2003, by NAFDAC and other agencies strangely revealed that container MAEU 610022/0 contained 20 x 1000kg bags of sand instead of milk. The second container (TRLU 468141/9) was examined on December 23, 2003 and was found to contain Glorie instant powdered milk in 25kg bags with the following details:-Batch No: 5/2003, Mfg. date: 10/2003; Expiry date: 10/2004.

We immediately issued an "Authority to Hold" citation to the Nigerian Customs Service and the Terminal Manager of Mid-Maritime (an inland container depot). A sample of the milk in container TRLU 468141/9 was sent to our laboratory for analysis, to ascertain its wholesomeness. The test results showed that the milk was wholesome and it was therefore released to the owners. The container of sand was referred to the Nigerian Customs Service. The sand issue remains a mystery to us.

In a similar incident, two containers out of 17 imported through Comet Terminal, Tincan Island Port, Lagos, by James Wallace & Co Limited of Lagos, manifested as standard food grade maize starch, was found on examination to contain sand. This case was also handed over to the Nigerian Customs Service to investigate.

Court Cases

FRN vs Jacob Amadi – Charge No. FHC/EN/46C/05

The accused person, Jacob Amadi, was arraigned before the Federal High Court in Enugu on a two-count charge filed on November 22, 2005, for being in possession of, as well as aiding and abetting fake drug producers with the printing of leaflets, labels, fake drug packets and other packaging materials. The fake materials were printed for *Supradyn* capsules, *Fansidar* tablets, *Fulcin* tablets, *Bethamethazone* and *Neomycin* (eye/ear drops), *Izal* liquid antiseptic solution, *Ampliclox* drops, *Fortune* injection, *Alcopar* tablets, *Zentel* suspension, *Halfan*

suspension, *Septtrin* suspension, TCP liquid antiseptic solution, *Combantrin* suspension, *Minizid* tablets, *Abidec* drops, *Nivaquine* syrup, *Neomedrol* solution, *Complan* drink and *Rifampin-300*.

Justice Olayinka Faji, in his judgment on March 7, 2008, found the accused guilty as charged on each of the two counts and sentenced him to five years' imprisonment on each count without the option of a fine. The terms were to run concurrently, effective from December 14, 2006, the date the accused was remanded in prison custody. The convicted man's lawyers pleaded with the judge for leniency and mitigation of sentence, stating that the accused person was a young man of 33 years, with five children, and that his dependants would suffer financially if he were sent to prison. They added that he had been in prison custody since December 2006 and had suffered enough to learn his lesson. In reviewing the plea for mitigation of sentence, Justice Olayinka Faji, stated: "The circumstances and nature of the offence are quite disturbing, especially when one looks at the list of drugs, which are everyday drugs, some for the use of children. It is therefore a matter for much concern that fellow humans can, for the purpose of monetary gain, resort to this kind of conduct. The activities of the National Agency for Food and Drug Administration and Control in the fight against fake and unwholesome drugs are beginning to yield fruit and that is better for the larger society. It is quite alarming that a young man of 33 years with five children will involve himself in a line of business that threatens the lives of children and could, in fact, affect his own life and those of his children." The judge, taking a very strong view of the accused person's activities, remarked that even though he was a first offender, "it is necessary to make it clear that production of counterfeit medicines is a dangerous menace, an indirect form of genocide. It should not be tolerated".

The court remarked that it was aware of Section three of the Counterfeit and Fake Drugs and Unwholesome Processed Foods (Miscellaneous Provisions) Act, which provides for an option of a fine for offenders, but that this would not apply in this case, as it would amount to allowing the accused person to use the proceeds of his dangerous business to pay for his crime. The five-year sentence is as against the maximum custodial sentence of 15 years.

FRN vs Nonye Iwunze – Charge No. FHC/K/CR/5/2005

The accused, Nonye Iwunze, was arraigned before the Federal High Court on a two-count charge for producing counterfeit medicines, and pleaded guilty to the charges. During the trial, the prosecution witnesses told the court how Iwunze was arrested by our officers in Kano, with the support of the police, following a tip-off. Our team found that the accused

was using his home as a manufacturing plant for the counterfeit medicines. The trial judge thereafter sentenced Iwunze to a term of five years imprisonment, with an option of a fine of ₦500,000 (US\$4350) on each count.

FRN vs Festus Osigwe – Charge No. FHC/PH/121C/06

The accused person in this case was arraigned before the Federal High Court, Port Harcourt for faking the popular Eva Table Water and Ragolis Spring Natural water. He bought empty bottles of these two major national brands, filled them with untreated tap water and used a soldering machine to seal the cover of the bottles. On arraignment, he pleaded guilty to the charges against him and was convicted and sentenced to 14 months imprisonment with the option of a fine of ₦15,000 (US\$130) by the court.

FRN vs Sixtus Agbaegbu – Charge No. FHC/ABJ/CR/97/2004

Sixtus Agbaegbu, a Civil Engineer, was alleged to be filling empty tins of the SMA brand of infant formula (baby food) with cassava flour, milk and sugar. He then took these tins to a supermarket at the Apo Legislative quarters in Abuja, Nigeria, where he sought to exchange them with the genuine products. The shop attendant noticed him and alerted the police. In his statement to the police, Sixtus confessed that his action was taken with the intention of exchanging his fake filled tins for good ones from the store. He also confessed that he had been in this business for some years. It should be noted that cassava contains cyanide, which is a potent poison and can cause death when consumed by babies. He was subsequently charged at the Federal High Court, Abuja. However, due to the inability of the police to produce Sixtus Agbaegbu for arraignment and after several adjournments by the court to enable them produce him, the court struck out the matter.

CHAPTER 13

FACTORS MILITATING AGAINST EFFECTIVE FOOD AND DRUG REGULATION

In our fight to safeguard public health in Nigeria, we encountered many challenges, but we were undeterred in our determination to rid Nigeria of the menace of counterfeit medicines and other substandard regulated products. The factors militating against effective food and drug regulation include corruption and conflict of interest, insecure and unfriendly environment, inadequate legislation, sophistication in copying technology, smuggling and various forms of evasion techniques, discriminatory regulations by exporting countries, ignorance and poor public awareness. Others include lack of political will, unfavourable government policies, political instability, inadequate co-operation among government agencies, chaotic drug distribution, scarcity of essential medication, irrational use of drugs and poor databases on health-related issues.

Corruption and Conflict of Interest

Principal among the factors that encourage drug faking worldwide is corruption and conflict of interest. Corruption is a driving force for poor regulation. In its guidelines for combating counterfeiting, the World Health Organisation (WHO) notes that the “efficiency of personnel is adversely affected by corruption and conflict of interest resulting in laws not being enforced and criminals not being arrested, prosecuted and convicted for crimes”.⁵⁵

Due to the prevalence of corruption in Nigeria, most stakeholders appeared to be contributing directly or indirectly to the dumping of fake products in the country. Some NAFDAC staff were not spared of this cankerworm. They engaged in practices such as the collection of unreasonably large quantities of samples for analysis, deliberately delaying registration processes and devising many other schemes which undermined and frustrated the products’ registration process, in order to extort money from manufacturers and their agents. On the part of the importers, dumping was the order of the day, as long as they could pay their way through the regulatory authorities. Some local producers did not pay much attention to their Good Manufacturing Practices (GMP) and the quality of their products. Distributors were

also involved in these corrupt practices, with some of them re-labelling drugs and other regulated products with the intention of extending their shelf life. Drug counterfeiters were prepared to pay anything to get their medicines registered or cleared at the ports. NAFDAC staff were constantly exposed to the temptations of bribery.

Too many people tried to use my relationship with them to get me compromised in the process of taking tough decisions. Sometimes, it was difficult for me because most of the drug counterfeiters come from the south-eastern part of Nigeria, where I am from. But, I was able to remain unwavering in all of my regulatory responsibilities. In fact, after a few months of uncompromising enforcement of rules, people became used to the unbending nature of the new regime and therefore left us alone to do the work without fear or favour. For instance, in 2001, two companies had a dispute over a trade name that was to determine which of them would have the right to register a product with NAFDAC. A schoolmate at the university and with whose family I had a good relationship deceived one of the companies into parting with a substantial sum of money. During the Christmas holiday of the same year, he came to my home in the company of a man I did not know, but who turned out to be an official of one of the feuding companies. Unknown to me, this was a ploy by my university friend to demonstrate the strength of our relationship to his companion. Consequently, he extorted ₦2 million (US\$17,391) from this company, purportedly as a bribe to make me take his side in their trade name dispute. The feuding parties attended a meeting to find ways of resolving the dispute by a panel formed by NAFDAC. After the panel, which I chaired, had examined the issues, we arrived at a decision that did not favour the company that had paid money to the 'friend' to win our support. They got angry after the meeting and openly expressed their disappointment and shock. Their behaviour puzzled me, and I warned them not to shout in my office. They actually thought that I had received their bribe and confidently expected the decision to be in their favour. I found out about this when they complained to my husband, that after sending money to me through a friend, I still did not decide the case in their favour. My husband told them that it was impossible for his wife to accept such money and advised them to go back to the person they had paid to get their money back.

During my first few months in office, a relative of my husband, who was a great benefactor to my family well before my appointment as Director General, had his unregistered margarine seized at the port by NAFDAC officials. He was asked to pay ₦200,000 (US\$1,739) as a penalty for the offence. He told them that his brother's wife was the Director General of

NAFDAC and that he was going to see me to resolve it, as he believed that the money would be waived because of our relationship. When he met me, I told him to go and pay the money so that we would not have a double standard that would compromise all my preaching about even-handedness in our enforcement activities.

In a similar circumstance, one of my husband's cousins living in London was unable to register any of the drugs of his pharmaceutical company for over three years because of poor documentation. He had come to me to facilitate their registration, but I refused when I read the reports stating that there were inadequacies in the documentation accompanying the applications. This strained our relationship until he died in 2008.

On another occasion, a Reverend Father came from Rome to collect some documents for research and was supposed to pay a stipulated fee for accessing the documents. Knowing that I am a catholic, the lady in charge of the section came to seek my permission to waive the payment for the priest. I paid for the priest instead of allowing the waiver, because I knew that such waiver would set precedence for others and would dent the structure that we were building in the new NAFDAC.

Normally, the first line of action by product counterfeiters is to compromise regulators. I had a hair-raising experience during my first month in office, when someone I knew visited me at work. He said he had listened to my statements and had come to offer me some useful advice. In his own words: "You are carrying out a government assignment and you should approach it as government work. Your way of carrying out the assignment should not be different from others. You can give the public the impression that you are doing a great job while at the same time making money for yourself. If you continue the way you are going and refuse to accept money from the 'drug people', they will kill you. Your position as Director General of NAFDAC will be filled within one week and people will call you a fool."

He told me that someone was ready and waiting to pay in ₦230 million (US\$2 million) into any account of my choice. He went on to give me his so-called "useful tips" on how to carry out my assignment. He described a scenario whereby if a drug counterfeiter imports ten containers of counterfeit medicines, the counterfeiter would tell me the container to seize. I would then communicate this information to my staff at the port, who should be part of the deal. They would seize the container identified by the owner and release the other nine. The public and the press would be alerted to the seizure of the one container, thereby deceiving them. In this way, the fake drug importer gets nine out of his ten containers of

counterfeit medicines released to him. In that way I, as well as the NAFDAC employees involved, would make a lot of money while the public would see us as doing our job, and everybody would be happy. I said to myself, what an ingeniously devious mind! I told him that I would never compromise on my stance against counterfeit medicines, not even for \$2 billion. For me, it is tantamount to drinking blood. I reasoned that if it were fate that I should be killed, so be it. I told him that if he ever came to my office again, I would have him arrested. He left in fear and muttered that he was only joking. I knew it was not a joke. My reaction actually scared him. I was in so much shock after his visit that I had several sleepless nights, pondering over the fact that NAFDAC and indeed other agencies had always made public seizures of fake or banned goods and yet the level of incidence of these products continued to be on the increase. Could the reality actually be the scenario that he painted?

On several occasions, when offending products were seized, their owners came to me in an attempt to negotiate the release of their products. I always told them that there was nothing to discuss, since I knew it was just a clever way of initiating bribery negotiations. In fact, after many failed attempts, by the end of 2001, my stand on these issues had become widely known and no one had the courage to attempt to discuss or negotiate anything with me. They even went as far as trying to engage my husband in discussions, asking him to advise me to soft-pedal, because it was very dangerous for me to wage a “drug war” against my own people! As I established the culture of rejecting bribes from counterfeiters, most NAFDAC staff followed suit, making the regulatory environment very uncomfortable for them. This zero tolerance to corruption by the new management team of NAFDAC was a rude shock to these criminals, who had expected to do business as usual. It got to the point that, even if I suddenly became interested in accepting bribe from the criminals, there would be no one ready to offer one because they would suspect it to be a set-up.

Insecure and Unfriendly Environment

When all their efforts at bribery failed, the criminals resorted to intimidation, harassment, blackmail and threats. They deposited fetish objects in our office, which included blood-stained feathers, African beads and a tortoise. They also made threatening phone calls to my husband and me. When they still did not succeed, they resorted to physical and arson attacks against our personnel and facilities.

The Attempt to Assassinate Me

In August 2001, six armed men stormed my residence in Abuja. They harassed and beat up my cook and lay in wait for me from 8pm to 10pm, hoping that I would return home. They did not steal even a pin, suggesting that theft was not their intention. As fate would have it, shortly before they arrived, I had travelled out to deal with an emergency in Lagos. I was alerted at about 4pm that my attention was needed to resolve a problem in our Operational Headquarters in Lagos. I boarded the 5.30pm flight from Abuja to Lagos. Upon arrival in Lagos, the officers were apologetic, saying that they had resolved the issue and had tried to reach me on the phone before I left Abuja. Fortunately, I could not be reached, hence my absence from my Abuja residence at the time of the siege. Surprisingly, the police officers on duty at my residence did not report for work on that fateful night and this was duly reported to the police headquarters.

On August 29, 2002, thirty armed men attacked and vandalised the NAFDAC laboratory complex in Oshodi, Lagos, destroying most of our sensitive equipment. This laboratory is the largest of its kind in West Africa. They harassed and stripped naked all the security men on duty and inflicted serious injuries on one of them. They smashed windows and doors and ransacked offices, stores and the various laboratories. Portable instruments and equipment, including desktop and laptop computers, weighing balances, pH meters and radiation measuring equipment were stolen. They destroyed bulky instruments like High Performance Liquid Chromatographs (HPLC), Gas Chromatographs, Mass Spectrophotometers, Atomic Absorption Spectrophotometers, Nuclear Magnetic Resonance Spectrophotometers, Uninterrupted Power Supply (UPS) systems, printers and the PABX communication systems. The invaders also broke into the instruments spares store and the sterile microbiology laboratory, destroying samples and exposing specimens. They selectively vandalised the new vehicles parked within the premises. The estimated cost of this vicious attack was ₦438 million (US\$3.81 million). Although the robbery and damage to the laboratory complex temporarily crippled our laboratory activities, the situation was speedily brought under control.

The culmination of these attacks was a failed assassination attempt on my life on December 26, 2003. Earlier, we had received security reports that some drug counterfeiters boasted that they would disgrace me by killing me in my hometown, Agulu, during the Christmas festival of 2003. My eldest son, Edozie, told me in October 2003 that he had had a very bad dream that I was shot in the village at Christmas and yet nobody had told him about the

threat prior to his dream. My second daughter, Somto, also had a horrifying dream some weeks before the shooting incident. In the dream, she saw an Internet headline announcing that I had been killed. She did not tell any of us, but only told her friend to join her in prayer for my safety. Again, no one had discussed the threat with her before the dream. As a result of the threat and my son's dream, my family and I decided not to spend the Christmas holidays in the village, even after we had repainted our home in preparation for the festive season. My husband and I told some of our relatives and friends that we would not go to the village for Christmas due to the threat. I also notified members of NAFDAC's Governing Council about the threat during our Council meeting on December 20, 2003. My family then decided that I would travel to South Africa with my children, and that my husband would travel to the USA with our youngest child. However, we could not obtain South African visas for my children because of time constraints. They arrived from the USA, where they were living, with one of their friends, Lela, on December 22, 2003, which made it impossible to process their visa applications. I thereafter thought of travelling to Ghana with my children and their friend, Lela, who had come to spend Christmas with us, but it was also too late to obtain a Ghanaian visa for Lela. I then decided to spend Christmas with them at our Enugu residence, which is about 50km from my village.

We stayed indoor from December 23–25, practically held hostage by fear of the threats from the drug counterfeiters. However, on December 26, 2003, I decided to attend a chieftaincy ceremony of a Council member at Orlu, in Imo State. I took my children and Lela with me, so that they could see the entertaining Igbo cultural masquerades perform. I believed that I would be safe, as long as I was not going to stay in the village. On the morning of December 26, 2003, I left Enugu for Orlu with three of my children, Lela and my brother, Dr Francis Edemobi. My brother and I were in my car, while the children rode in another car behind us. I also had in my entourage five police officers, a State Security Service (SSS) officer and my personal assistant. We stopped at Agulu at about 12 noon to see my mother-in-law and spent a few minutes with her. She lamented that we did not come to spend Christmas with her in the village, but I told her that it was too risky for me to stay in the village because a fake drug baron and his gang had threatened to kill me in the village. We also stopped at Nanka to see my cousin Obi Adimorah, after which we moved on to Orlu for the chieftaincy ceremony. Intuitively, as Obi was walking us to the car, he expressed concern that I was not travelling in a bulletproof car and that he was going to buy one for me in due course. I did not take the statement seriously. On our way back to Enugu from Orlu, I decided to stop at Agulu once again, to say goodbye to my mother-in-law. A few

metres from our village house, my driver overtook the pilot car to prevent the driver of the pilot car from driving past the road to my in-laws house, because he had not been informed that we were going to stop to see my mother-in-law for a second time. At that point, we suddenly heard loud bangs, which I thought were sounds from Christmas fireworks. The bangs were actually from gunshots. Within a split second, there was a painful bang on my head, which made my scalp hurt badly. A bullet had just shattered the rear windscreen of the vehicle, pierced my headscarf, burnt my scalp like hot water and gone out through the front windscreen. It was so painful that I thought the bullet had hit my skull (Figures 7–9).

The police officer attached to me, who was sitting in the front of my car, urged the driver to speed on, and used his walkie-talkie to direct the driver of the pilot car to prevent any vehicle from overtaking us. In the midst of the shooting and resulting pandemonium, people ran helter-skelter for their lives, cars hit one another, my convoy was disorganised and I did not know where my children were. We drove on and did not divert to our village house at Agulu. We continued straight on and decided to go to Awka police station to make a report. On the way, I asked my brother to touch my head to find out if there was blood. He did and showed me his fingers, which showed that there was no blood on my head. My children then caught up with us at the police station in Awka. I even told the officer in Awka that a bullet had entered my head and he said: "Madam, if bullet entered your head, you will not be talking."

I had thought about going to the hospital, but following the police officer's statement, my concern for the safety of my children and their foreign friend, and the fact that there was no opening or blood on my head, I decided to go back to my house in Enugu. I later learnt that some of the bullets aimed at my car riddled a commercial bus and unfortunately, the driver of that bus, Mr Emeka Onuekutu, was hit and died instantly. My life, the lives of my brother, my children, our foreign visitor, staff and security details were saved. However, my heart still goes to the family of the bus driver who was killed by the bullet aimed at me.

On the morning of December 27, 2003, some young men went to the University of Nigeria Teaching Hospital at Enugu, where I live, and told the doctor at the emergency section, Dr Okezie Mbadiwe, that they were sent by their boss at the police station at Awka to find out how I was after a ghastly motor accident the previous evening. They claimed that they were asked to protect me if I was still alive. The doctor expressed surprise, and told them that they had no information about any accident involving me. The young men then asked for my home address since they knew my husband was a doctor in that hospital. The doctor

declined, as it is hospital policy not to give the addresses of their doctors to strangers. The next day the doctor heard about the attempt to assassinate me.



Figure 7: Assassination Attempt –Shattered Rear Windscreen of the Car



Figure 8: Assassination Attempt – Headscarf Showing Bullet Holes



Figure 9: Assassination Attempt – Car Front Windscreen with Bullet Hole

Following the assassination attempt, the suspects were arrested and arraigned before an Abuja High Court. It was easy for the security agencies to link them with the crime since the drug counterfeiters had boasted some months earlier, that the Director General of NAFDAC would not live to see the year 2004. This case was tried for about two years. Fifty-eight exhibits were tendered and 19 witnesses gave detailed testimonies of every stage of the assassination attempt, from planning to execution and even post-shooting. One of the suspects “hired” to shoot me at a fee of ₦10 million (US\$86,957) was a star witness for the prosecution.

At the end of the trial, the presiding judge ruled that he had no jurisdiction to hear the case, even if the issue of jurisdiction was raised three times by the prosecuting lawyers at the beginning of the hearing, but was set aside by the judge. He discharged and acquitted the accused persons and advised that the case be tried in Anambra State in south-eastern Nigeria, where the shooting took place. The Attorney General of the Federation appealed the ruling at the Appeal Court at Abuja and the decision was overturned. The Abuja High Court judge was subsequently directed to continue with the trial of the case. Since this ruling, all attempts to re-arrest the accused have failed. Security agencies have been searching for the accused,

but could only re-arrest three out of the six. One of those arrested was granted bail due to poor health. There were some startling revelations from the witnesses during the court hearing, which still give me sleepless nights. As I conclude this book, the witnesses are being harassed, threatened and hunted by the masterminds of the assassination attempt. The case is yet to be concluded, six years later.

Three months after the assassination attempt, between March 7 and 11, 2004, NAFDAC's facilities across the country were attacked and burnt. On March 7, 2004, our Lagos office complex, at the Federal Secretariat, Phase II in Ikoyi, Lagos, was gutted by fire, which reduced it to ashes and debris. Our Lagos office complex, being our Operational Headquarters, is the nerve centre of our activities. NAFDAC occupied about 95 per cent of the office space in the affected wing of the building. According to eyewitness accounts, the fire started at about 9pm from the 11th, 4th and 2nd floors, simultaneously. It quickly spread to other floors of the building. The offices of the Director General, Establishment Inspection, Ports Inspection, Registration and Regulatory Affairs, Accounts Department, Records Office and Cash Office were all burnt down. Some cash, and most financial documents, were in a fireproof safe and were saved. Office equipment including computers, photocopiers and fax machines were all destroyed. The completed Local Area Network (LAN) linking our activities in the office complex and the NAFDAC Registered Products Automated Database (NARPAD) were all destroyed. From the pattern of the fire, eyewitness accounts and the report from the estate manager of the Federal Secretariat, it was strongly believed that our office complex was the real target. Although other Federal Government organisations occupied different wings of the twelve-storey building, only the wing housing NAFDAC offices was burnt down. It was obvious that the intention of the arsonists was to destroy our ability to perform our statutory functions effectively. (Figures 10 & 11).

On the same day, a friend of mine, one of the foremost drug manufacturers in the country, had her factory burnt down in Lagos. She had earlier organised a reception to celebrate the Integrity Award bestowed on me by Transparency International (TI). This was a frightening coincidence.



Figure 10: Burnt NAFDAC Operational Headquarters, Lagos (Outside View)



Figure 11: Wreckage of NAFDAC Operational Headquarters, Lagos, Destroyed by Fire (Inside View)

On March 10, 2004, barely 72 hours after the fire incident in our Lagos office, our laboratory complex in Kaduna was set ablaze and razed to ashes. Again, eyewitnesses reported that the fire started simultaneously at all corners of the complex at about 3am. The entire building, laboratory equipment, chemicals and reagents, furniture and office equipment were destroyed by the fire. State-of-the-art equipment such as High Performance Liquid Chromatographs (HPLC), Atomic Absorption Spectrophotometers (AAS), and Gas Liquid Chromatographs (GLC), Ultraviolet-Visible Spectrophotometers, Infra Red Spectrophotometers (IR), Turbidimeters and vital documents in the complex were destroyed. Most of the equipment were new and some were still in their original boxes, awaiting the completion of site preparation for installation. The destruction, valued at about ₦228 million (US\$1.98 million), was a colossal loss to NAFDAC. It was a major setback to our operations. Preliminary investigations revealed that none of the three police officers guarding the premises was on duty on the night of the arson. They were withdrawn a few days before the inferno, without any notice to NAFDAC. Only the officers of the private security company contracted by NAFDAC were on duty as was the case when six armed men invaded my residence in August 2002 and the policemen on duty did not report for work that night (Figures 12 & 13).



Figure 12: Wreckage of NAFDAC Kaduna Laboratory Complex Destroyed by Fire (Outside View)



Figure 13: Wreckage of NAFDAC Kaduna Laboratory Complex Destroyed by Fire (Inside View)

A few days after the burning of our Lagos and Kaduna facilities, a building adjacent to our Benin office was burnt down. We believe that the real target was our office complex. In the same week, criminals broke into the premises of our laboratory complex in Maiduguri, gaining entrance through a hole they bored in the fence. Fortunately, they were chased away by the security agents in the premises.

These attacks generated tremendous outrage from within and outside the country. Surprisingly, when the first arson attack was reported to the Inspector General of Police, he downplayed it, insinuating that my security operatives might have been responsible for the attack. On the contrary, members of the committee on National Security and Intelligence of Nigeria's House of Representatives immediately adopted this issue as one affecting national security and ordered the Inspector General of Police to appear before the committee. Several groups strongly condemned the attacks by the arsonists. PMG-MAN showed their solidarity with NAFDAC by organising a programme captioned "All Hands on Deck", to drum up support for NAFDAC from individuals, government and NGOs. The Federal Government issued directives to the police and State Security Services (SSS) to beef up my security, and that of

all NAFDAC facilities and offices nationwide. This was promptly done. Ordinary Nigerians were not left out in the condemnation of these reprehensible acts. The public also demanded that the attacks be thoroughly investigated. Associations, individuals, students and children voiced out their revulsion of the attacks. Their voices were heard through the radio, national dailies, television programmes and the numerous letters they wrote to NAFDAC. The media also lent their voice to the general call for full investigations and justice. The Agency was literally flooded with messages of support from the public. Many organisations, both local and international, made donations to NAFDAC. These provided us with the encouragement we desperately needed at that time, in the face of such highly coordinated attacks.

In early 2004, three friends of mine suggested that they wanted to organise a Thanksgiving for my survival to coincide with my 50th birthday, which was coming up on July 14, 2004. I gladly accepted because my family was also thinking of organising a Thanksgiving service and reception to thank God for my survival from the assassination attempt. I asked my friends to print a sample of the invitation card for my vetting. When they brought the card, I noticed that there was no name under the RSVP. I suggested that they should have either their own or their company names on the cards so that people would know who the organisers were, in order to reach them if necessary. They all kept quiet for a few seconds, then one of them spoke up, “Madam, nobody wants his name or company name on your card because drug counterfeiters are so vicious that they could target our factories for arson”. Very painfully, it dawned on me that none of them wanted to publicly associate with me because of their safety.

NAFDAC Employees’ Response To The Arson Attacks

Even though we were rattled and a bit discouraged, we did not want the counterfeiters to defeat us psychologically. In Kaduna, we immediately converted five bungalows meant for staff residential quarters into laboratories and our laboratory activities continued in earnest. Presently, work is at an advanced stage in putting up a modern laboratory complex in Kaduna, while we are still operating in the temporary laboratory.

In the same vein, on March 8, 2004, after the burning of our offices in the Federal Secretariat, Lagos, I called a meeting of all members of staff in my house and told them that we should never show any sign of defeat. Consequently, I directed the Enforcement Director to carry on with the screening of some drug shops scheduled for that day. He was quiet for some seconds and I wondered aloud why he was not responding to my instruction. He simply

commented: "The smell of the smoke is still in the air." I gave up for that day. On the next day, President Olusegun Obasanjo instructed the Minister of Housing and Urban Development, Mrs Mobolaji Osomo, to allocate any available Federal Government property in Lagos to NAFDAC to use as temporary offices. We followed up on this with a letter to the Minister the same day, informing her of a space that was available at 23 Temple Road, Ikoyi, Lagos. She granted our request. Though the main building measuring 172m² was burnt, we were prepared to renovate the attached service quarters in the compound. I addressed the staff members and told them that we could not afford to step down our work, as that would mean victory for the counterfeiters. They all agreed and we immediately relocated to Temple Road, an open land space with trees that provided shade under which we worked. We also put up emergency plastic canopies. Emergency official stamps were quickly carved. We bought tables and chairs from roadside carpenters. During that period, an insect bit one of our staff, Mrs Ijeoma Nwankwo. The spot became swollen and turned red. She went to the hospital and was given medication. Six days later, tiny maggots began to come out of the swollen spot and three bullet-like holes were left at the spot on her body. This horrible experience forced us into building makeshift shelters of corrugated aluminum sheets with cement floors. We then mounted ten Portakabins, six of which were donated by Mr. Tonnie Iredia, the then Director General of the Nigerian Television Authority (NTA). The existing service quarters were renovated for office use. A long block of ten rooms measuring 414m² was constructed. Staff members even pitched in, carrying bricks and water for the construction. In all, we created a total office space of 586m². Part of my official residence in Lagos was also converted into an office. We only lost a few working days after the attack in Lagos. We retrieved some lost documents from our records in other state offices and from laptops, which most staff members carried home with them.

After one year, when we were ready to develop 23 Temple Road, we faced challenges getting approval from the Lagos State Government because the property is located in an exclusively residential area. We therefore decided to use the Portakabin at our Oshodi laboratory complex. As I conclude this book, the Lagos State Government has approved another site at Apapa for our new Operational Headquarters in Lagos. We have completed the soil test and the pre-qualification bids. The next step is to advertise for financial bids once the technical drawings and the bill of quantities are received from the Federal Ministry of Housing and Urban Development. The Agency still faced many challenges as it operated from the Portakabins, office spaces in the laboratory and one of the warehouses in the same compound. On one occasion, a snake was found in one of the Portakabins as staff members reported to

work. In spite of this discomfort, NAFDAC continued to work round the clock and was consistently rated by public opinion polls as the best government agency in the country.

My family had their fair share of attacks from the drug counterfeiters. In 2003, my youngest child Obumneme, who lived with us in Nigeria, narrowly escaped a kidnap attempt by claiming that I was not his mother but his aunt when accosted by men who tried to kidnap him. My husband and I had decided that Obumneme should stay in Nigeria because it was too early in his life to allow him to migrate and join his siblings in America. My other children moved to the United States of America in 1997 after I won the US Visa Lottery in 1996. However, after the kidnap incident and against his wishes, we had to send him to the USA to live with his siblings.

My youngest child had always worried about my safety because of my job. In 2002, he told me a story about the challenges he faced in school from his peers. His mates had taunted him by accusing his mother of burning peoples' money. I asked him if he believed the accusation that I was burning peoples' money and his answer was yes! My son did indeed agree that my burning counterfeit medicines and unwholesome food products, imported illegally into the country by criminally minded persons and organisations, was tantamount to burning their money. I tried very hard to explain to him that fake medicines were not the same as money and destroying them to avoid their getting back into circulation, in order to protect public health, was not the same as burning peoples' money. However, no matter how hard I tried, he would not agree with me. To him, counterfeit or no counterfeit, money would be realised if the drugs were sold. Therefore, burning them was the same as burning their money and they had reason to be bitter. Then he asked me: "Mum how long have you got left in your tenure as Director General of NAFDAC?" Then he added: "I am asking because I am scared stiff." I replied that it was a five-year tenure, which would end in April 2006. He sighed and bit his lips, made a calculation with his fingers, and began a countdown to April 2006. Obumneme swore that I must quit the job at the end of the tenure and sustained his campaign until my husband publicly declared that the family had decided that I would quit the job at the end of my first tenure.

When Somto, my second daughter, went for the Idols West Africa competition in February 2007, the judges asked her if she was related to the NAFDAC boss and she answered: "We are from the same family." A friend of mine excitedly called me on the phone and said: "Are you watching Idols? Your daughter just denied you!" On many occasions, my husband received

telephone calls demanding that he should restrain me from destroying some people's means of livelihood and that if he could not stop me, both of us would face the consequences.

On Monday December 1, 2008, some unknown gunmen kidnapped Dr Francis Edemobi, my younger brother, the Chief Executive Officer of the Paul and Grace Foundation, a Non-Governmental Organisation (NGO) in Enugu State, Nigeria. The kidnappers drove into his building site at Enugu in a black Mercedes Benz 230E at about 11am and forcibly abducted him. They initially demanded a ransom of ₦30 million (US\$260,870) for his release, but later increased it to ₦50 million (US\$434,783). They said that if the money was not paid my brother would be killed.

We were all very confused and anxious because we could not afford such a huge amount of money. Some of my friends started raising what money they could. A very close family friend volunteered to pay the money to secure my brother's release, but I refused. I believed that paying the kidnappers to free my brother would amount to caving in to these unscrupulous persons, which would likely encourage others to follow suit in order to extort money from the family. While we kept praying for his safety, I urged the police to intensify their search and efforts to free my brother. We also involved the State Security Service (SSS), who were working in concert with the police to rescue him. On many occasions, the kidnappers would call us while he was being tortured and we would hear him scream and shout in pain. In the four days that my brother was held hostage, we went through unforgettable grueling experiences. The kidnappers told my brother's manager that I burnt their client's drugs worth ₦82 million (US\$713,043) and that they would not negotiate over the ransom because I did not negotiate before burning their drugs. At another time, they threatened to shoot one of his legs to show us that they were serious about the money. On another occasion still, they said they were going to cut one of his fingers off and send it to us to identify. While in captivity, his hands and legs were tied with ropes. He was blindfolded so he did not know where he was nor the difference between day and night. He actually thought that he had stayed longer than the four nights and four days that he spent in the custody of the kidnappers.

On Friday December 5, 2008, a Good Samaritan reported to the police that the kidnappers were keeping my brother near Ebeano Tunnel in Enugu metropolis. Armed with this information, the special police anti-robbery squad in Enugu led by DSP Jude Agbanajelu requested permission to storm the hideout of the kidnappers to free my brother. My family agreed with palpitations. I knew this was a dangerous option, but my faith gave me the courage to support the police plans. During the rescue operation, the leader of the gang was

shot dead, while two others were injured. My brother was rescued without injury. One of the kidnappers made some very revealing confessions, which led to the arrest of five more people. The case is currently in court.

The counterfeiters have also continued their attacks and arson against NAFDAC staff and facilities. On July 7, 2004, NAFDAC officials in Gombe State set out for scheduled surveillance activities at Kwami, Funakaye, Nafada and Dukku Local Government areas. The mission was to sample infusions and solicit the support of the Local Government Chairmen in curbing the practice of drug hawking. Inspection activities were successfully carried out in the first three Local Government areas, but the story was different in Dukku. The officers narrowly escaped being lynched and their official vehicle was damaged by an angry mob organised by drug hawkers. They angrily issued threats, shouting that no authority could stop them from hawking drugs. Their statements tallied with threat letters that were earlier received in our Gombe office in 2003. With the charged atmosphere and chants of “Kill them!” and “To hell with NAFDAC!” the officers fled for their lives, with the assistance of some mobile police officers.

The incident was reported to the Governor of Gombe State, Alhaji Mohammed Danjuma Goje, the Police Commissioner, the Director, State Security Service and His Royal Highness, the Emir of Gombe. The Governor immediately directed the Police Commissioner to beef up security around our officials and to ensure that the hoodlums were apprehended and prosecuted. He also directed the Local Government Chairman to assess the damaged vehicle and repair or replace it. To create more awareness of the implications of such threats and attacks on our officers discharging their regulatory duties, I paid a two-day working visit to Gombe State. I visited the Governor and the Emirs of Gombe and Dukku, soliciting their support for our activities. The Emir of Dukku profusely apologised for the attack and promised that he would be more vigilant to ensure that such a thing never happen again in his domain. The officer in charge of Gombe State was so much under threat that he relocated his family out of the State. Tearfully recounting his ordeal to me, he said that what saddened him the most was his temporary separation from his immediate family, especially his young children. During my visit to Gombe, I visited the Emir of Biliri on his request. He actually invited me to come and talk to the youths who were destroying themselves with locally brewed gin known as Ogogoro.

In June 2006, NAFDAC officers were attacked when they went to the drug market in Onitsha, following reliable information that indicated the presence of large quantities of counterfeit

medicines in a section of the market. In the process of screening the shops to remove counterfeit drugs they were assaulted and driven out of the market by the traders of the counterfeit medicines. Six of their operational vehicles were vandalised and 12 out of the 13 police officers who accompanied them fled. It was a miracle that our officers escaped alive.

Again, on June 13, 2007, NAFDAC inspectors, led by Ijeoma Nnani, had gone to confiscate unwholesome drug products in Kano market in the company of ten armed police officers. They were assaulted and forcefully prevented from doing their work. One of the investigators, Mr Momodu Segiri, sustained multiple fractures in one leg and our operational vehicles were vandalised. The police officers who accompanied them were over-powered and had to radio for reinforcements. It took the intervention of 200 police officers with an armoured tank to disperse the raging mob of fake medicine traders and rescue the NAFDAC agents.

NAFDAC South-west zonal office and NAFDAC Oyo state office are both located at the Federal Secretariat in Ibadan. For many months, the “strong man” of Ibadan politics, the late Chief Lamidi Ariyibi Adedibu, made it impossible for NAFDAC officials to carry out their routine regulatory activities. Whenever fake products were seized, he would give orders for their release. On one occasion, NAFDAC inspectors had sealed off a warehouse in which tainted fish was stored in order to prevent the fish from being sold to the public. Unfortunately, Chief Adedibu instructed his aides to re-open the warehouse. NAFDAC officers reported to the police, but Chief Adedibu appeared to be too powerful, and the police did not intervene. This incident prompted me to urgently convene a stakeholders’ workshop in Ibadan, in November 2007. I used the opportunity of my travel to the state to pay a courtesy visit to the State Governor, Otunba Alao Akala. During the visit, I complained to the Governor that Chief Adedibu was harassing, intimidating and terrorising NAFDAC staff, thereby obstructing our regulatory activities, which was becoming a great hindrance to our fight against counterfeit medicines. The Governor promised to speak to him about the issue. Next, I visited the traditional ruler of Ibadan and laid the same complaint. He too, promised to do something. After the two courtesy visits, I went to the venue of the workshop. On my arrival, some people came to whisper in my ear that I must leave Ibadan immediately for having dared to openly take on the Ibadan “strong man”. I refused to be cowed and stayed until the next day as planned. Some people actually told me that I was lucky not to have come from that part of the country, or Chief Adedibu’s thugs would have burned down the property of people related to me. Thereafter, the police charged Chief Adedibu

and took him to court. He abused me publicly, saying that I was antagonistic to him because he did not help me to become a Minister in Nigeria. I briefed my lawyer, Mr Ken Odidika, and instructed him to file a libel suit against him. Eventually, I was advised by my family and friends to discontinue the case because it would become a distraction to my work. Chief Adedibu also wrote a letter abusing and threatening to sue me, but he never did. He died shortly after.

In April 2008, our officers in Abakaliki, Ebonyi State, went to a provisions store located in the auto spare parts market, to investigate a consumer complaint in respect of an extraneous substance (a ₦20 note) found in a bottle of Vitamalt drink. The bottle in question, along with other expired drinks found in the store were confiscated and the shop was sealed. An angry mob instantly gathered and the Chairman of the market ordered the arrest of our officers and their police escort. The mob re-opened the locked shops, locked the market gates to prevent our officers from leaving, and the items the agents had confiscated were forcefully retrieved from them. Fortunately, the supervisor of our team contacted the Commander of the Abakaliki Military Cantonment, who immediately dispatched armed soldiers to rescue our officers.

On May 12, 2008, our Regulatory Officers in Borno State were attacked while on duty arresting fake medicine hawkers in Damboa market. The hawkers were arrested and their drugs seized. A surging crowd immediately gathered, chanting religious songs to give the issue a religious connotation. Both our officers and their police escort were chased out of the market and the town. The angry mob took back the seized drugs and set the hawkers free. Death threats were issued against NAFDAC officers. They reported the incident to the head of the police in the area (Divisional Police Officer) who promised to look into the matter. I also reported the incident to the State Governor, Alhaji Ali Modu Sheriff, and he promised to improve the security around NAFDAC staff.

On May 20, 2008, NAFDAC officers, along with some police officers on routine surveillance at Ejule village market in Ofu Local Government Area of Kogi State, were attacked and chased away by youths who brandished machetes and carried stones. In the process, they lost their phones and left the confiscated products behind. Because of this attack on NAFDAC staff, I paid a visit to the Governor of Kogi State, Alhaji Ibrahim Idris and the traditional ruler of Ejule, the Ogohi of Ejule, Chief Akwu Obaje, to lodge a complaint about this attack. Stakeholders' meetings usually follow such courtesy visits. Chief Akwu Obaje donated a building to us for use as a small NAFDAC office for Ejule Local Government

Area. While in Kogi State, I also visited the traditional ruler of Okene, HRH the Ohimayi of Igbira Land, Alhaji Ado Ibrahim, who also offered us land to build a small NAFDAC office in his domain. The support we got from the Governor, the traditional rulers and stakeholders who thronged out en masse to receive our messages and ask questions was very encouraging.

We have also documented over 20 other attacks against NAFDAC officers in different parts of Nigeria.

Fighting the war against fake drug barons had taken its toll on me and my family in so many ways, and I felt that taking a break was not a bad idea. However, both individuals and organisations, pleaded with my husband and I to have a rethink. The then President of Nigeria, Chief Obasanjo, very kindly invited my husband to his residence, to reassure him that the Government would provide me with all the necessary protection I needed to perform my duties. I took time out to think things through. Although I needed to listen to my family, I also believed that quitting at that point would have meant victory for the drug counterfeiters. They had already started to celebrate openly upon hearing the announcement by my husband in which he said that my family did not want me to continue with the job. They popped champagne and exchanged gifts and handshakes rejoicing that the “NAFDAC woman” had finally thrown in the towel.

Realising how desperate the drug counterfeiters were to terminate my life, the Nigerian Government ensured that I was always guarded by at least eight armed police officers wherever I went. Police officers also guarded NAFDAC officials as they conducted regulatory activities. Our offices in all the 36 states of Nigeria were also well protected.

Inadequate Legislation

In most countries, laws against drug counterfeiting are weak and inadequate. Consequently, criminals are shifting from gunrunning and cocaine pushing to drug counterfeiting, as it is financially more lucrative and the risk involved is relatively low.

Nigeria's drug control laws were very weak, non-deterrent and unwieldy. They were overlapping and sometimes conflicting with other laws. Some of the laws were outdated, and needed to be updated to meet present-day realities for effective regulation. The penalties for dealing in counterfeit medicines or other fake regulated products in Nigeria ranged from imprisonment of three months to five years, or the option of a fine of ₦10,000 (US\$87) to ₦500,000 (US\$4347). In order to make the laws stiffer, we reviewed the existing legislation

and forwarded proposed amendments to the National Assembly in 2001. The highlight of the review was that life sentences should be meted out to those convicted for manufacturing and dealing in fake and counterfeit medicines. We have continued to review and resubmit the laws on several occasions on the request of the lawmakers for amendments.

The nation's weak laws were further hampered by abuse of the judicial process, granting of inordinate injunctions to counterfeiters, long delays of trials and other handicaps.

Despite the criminality of drug counterfeiting, the perpetrators, who are usually very wealthy, often go scot-free in court. On many occasions, they take advantage of the slow pace of the court process and in other cases, circumvent justice. Below are some examples of how cases were frustrated in the courts:

- i. Some cases became so protracted that the judges were either transferred or died in the process and the cases were started all over again.
- ii. On one occasion, a lawyer contracted by NAFDAC to prosecute a high-profile case claimed that he lost all the documents for prosecuting the case.
- iii. On another occasion, our lawyer (a Senior Advocate of Nigeria) signed to settle out of court with the defendant's lawyer without NAFDAC's permission.

We have had some important cases, some of which have been in court since the 1990s. A few examples are as follows:

FRN Vs Marcel Nnakwe and ANOR – Charge No.: FHC/EN/20C/2001

Marcel Pharmaceuticals is located at 17 Palmer Road Onitsha, and owned by Chief Marcel Nnakwe. Before I became the Director General of NAFDAC, four consignments of counterfeit medicines were seized from Marcel Pharmaceuticals between 1996 and 1998.

The first consignment was seized in December 1996, and consisted of fake Indomethacine 10mg Capsules (anti-arthritis) labelled and sold as Chlordiazepoxide (Librium) which is a sedative.

Chief Nnakwe was arrested and charged to court at the Eastern zone of the defunct Miscellaneous Offences Tribunal in July 1997. In the same month, Chief Nnakwe imported another consignment of fake Indomethacine 10mg and 25mg capsules.

All efforts made to re-arrest Chief Nnakwe for this second offence were thwarted by a series of court injunctions and orders. In one such judgment at the Federal High Court

Enugu, NAFDAC was restrained from arresting or detaining personnel, investigating the company or sealing its shops or impounding its vehicles.

Again Chief Nnakwe continued the importation of counterfeit medicines due to the court orders such that by September 1997, he imported consignments of a fake injection labelled Vitamin H3, Chloramphenicol capsules and expired Ceeh Ceeh cream. They were imported with a fake name and a non-existent address, and falsely labeled as PVC garments. With the cooperation of NDLEA officials in Port Harcourt, the consignments were traced to Chief Nnakwe. In 1998, Chief Nnakwe imported another four containers of counterfeit medicines through the same Port Harcourt wharf. They were meant for auctioning by some customs officials when NAFDAC officials stepped in to stop this. It is important to note that Chief Nnakwe must have escaped with many other containers. The cases listed were those that NAFDAC was able to confiscate.

Despite these multiple importations of fake and expired drugs by Chief Nnakwe, NAFDAC was handicapped by court injunctions.

In June 2001, there was another case of importation of fake Alabukun powder connected to the Chief's son. During investigation on this case, we were assisted by the drug sellers in Onitsha market (who had pledged their loyalty to the new NAFDAC) to locate their warehouses at Fegge, Onitsha. One thing led to another until Chief Nnakwe forfeited the fake and expired drugs for destruction and tendered a public apology to Nigerians.

On July 13, 1998, the Federal High Court Enugu set aside part of the earlier orders including the one staying proceedings of the Miscellaneous Offences Tribunal. Chief Nnakwe appealed against this order and filed an application for stay of execution of the order and stay of proceedings of the Miscellaneous Offences Tribunal.

Thereafter, the Miscellaneous Offences Tribunal was scrapped in 1999 and NAFDAC applied to the Federal High Court for appropriate transfer. The application by Chief Nnakwe dragged on until November 21, 2000, when it was struck out. Within 24 hours of this decision, Chief Nnakwe's counsel filed another application to relist the matter and this was granted. The court eventually heard the application and dismissed it on September 2001.

Vipfarm Industries vs NAFDAC and ORS – Charge No.: FHC/L/CS/238/98

NAFDAC intercepted 28 lorryloads of suspected counterfeit medicines imported into Nigeria by Vipfarm in 1995. The company's Managing Director, Fred Huang, and General Manager,

Joseph Huang were prosecuted the same year. The court granted Vipfarm interlocutory relief, directing NAFDAC to release some of the suspected counterfeit medicines. Whilst the Agency appealed against this decision, Vipfarm filed a contempt case against NAFDAC officials. When NAFDAC refused to release the consignment of counterfeit medicines to Vipfarm, they filed a civil suit against NAFDAC in 1996, seeking damages and other consequential losses amounting to ₦600 million (US\$5,217,391), at 21 per cent interest accruing from August 4, 1995. This case has been in court since 1995 and a decision on whether the drugs are, in fact, counterfeit and should therefore be destroyed, is yet to be made.

FRN vs. Christopher Ezenwa and ANOR – Charge No.: FHC/L/162C/99

On September 27, 1999, Chief Christopher Ezenwa, Managing Director of Chez Pharmaceuticals Limited and his company were arraigned at the Federal High Court sitting in Ikoyi, Lagos State, before Justice D.D. Abutu, on an eight-count charge of unlawfully and intentionally importing counterfeit, substandard and adulterated drugs from England into Nigeria. The items imported were:

- 80 cartons of Mosaquine tablets (100mg), a brand of Chloroquine Phosphate with the cover name of Harmless Pharmaceuticals.
- 77 cartons of Paracetamol tablets (100mg) with the cover name of Harmless Pharmaceuticals.
- 64 cartons of unlabelled pharmaceutical products found to contain Paracetamol (100mg).
- 167 cartons of unlabelled pharmaceutical products found to contain lactose and starch.

On April 22, 2005, after series of adjournments, the accused persons were convicted on each of the eight charges. They were sentenced to six months' imprisonment, with the option of a fine of ₦100,000 (US\$869). This case lasted for about six years.

Pure Water in Rivers State

On May 19, 1999, Justice Melford Goodhead, sitting in one of the State's High Court, in Rivers State, granted the request of some pure water producers by issuing an injunction restraining NAFDAC from monitoring the operations of the applicants. From the date of that order until the end of 2002, the motion on notice, which they filed in 1999, was not heard. This rendered us helpless in the regulation of pure water production and sale in Rivers

State for three years. The applicants photocopied the court order and circulated it to other pure water producers. They brandished the notice before our officers whenever we went to sample their water for compliance with safety and hygienic standards.

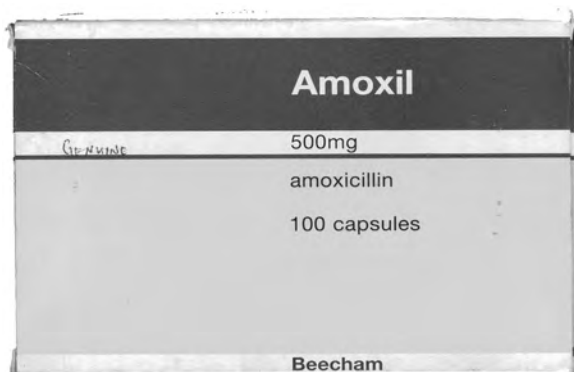
Global Soap and Detergent vs NAFDAC – Charge No.: FHC/1L/CS/24/2002

The Ariel detergent controversy arose in 2002, from a complaint lodged by Procter and Gamble (Nigeria) Limited, alleging that Doyin Group of Companies, a Nigerian company, was producing a counterfeit version of their popular Ariel detergent powder. Our investigations led us to believe that Global Soap and Detergent Industries Limited, a subsidiary of the Doyin Group, was indeed secretly counterfeiting the detergent powder. Laboratory analysis of the samples showed that the suspected counterfeit version was substandard. It failed a critical parameter test; the Total Active Matter (TAM) index, an indicator for determining the potency of a detergent. This Ariel also had labelling attributes of a counterfeit product. It had no manufacturer's name, no date markings, no batch number and an incomplete location address for the manufacturer. Global Soap and Detergent had registered some products with NAFDAC, but had never applied to register this particular product. Consequently, NAFDAC placed the production line of the 'so-called' Ariel on hold. Rather than complying with our directives, the company embarked on a wide media and political campaign against the Agency, and employees of Global Soap and Detergent demonstrated at the Kwara State House of Assembly, falsely claiming that their entire factory had been shut down by NAFDAC. At the Ilorin Federal High Court, an injunction was granted in favour of the company restraining NAFDAC from closing their manufacturing lines or interfering with the production of the detergent. However, Global Soap and Detergent Industries Limited eventually opted for an out-of-court settlement and gave a written undertaking not to produce Ariel detergent until a final decision was given in their trademark dispute against Procter and Gamble by the Federal High Court sitting in Lagos. Doyin Group of Companies won the case in December 2007 but Procter and Gamble appealed against the ruling at a higher court.

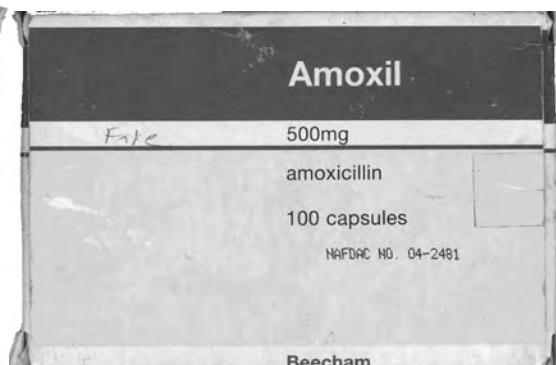
Sophistication in Copying Technology

Product counterfeiting is made easier by the increasing sophistication of technologies in drug production. Cloning of fast-moving drugs is so efficient that even brand owners find it difficult to differentiate between the counterfeit and the real products. Figures 14–19 show a few examples of clones intercepted in the course of our regulatory activities.

Original



Fake



- Blister has **grey**, **red** and **white** diagonal bands
- Each blister has “**SB102M**” **embossed** on the edge
- Registered by NAFDAC
- NAFDAC reg No. **04-2481** **printed** on the pack

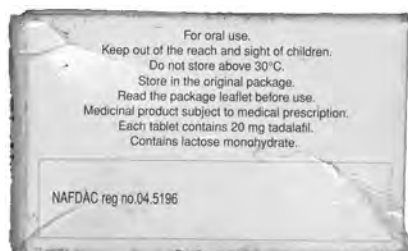
- Blister has **grey** and **red** diagonal lines only
- There is **no** company identification on the blister
- **Counterfeit** product with copied NAFDAC reg No.
- Not registered by **NAFDAC**

Figure 14: Sound-alike/Look-alike Counterfeit: *Amoxil*

Original

Fake1

Fake 2



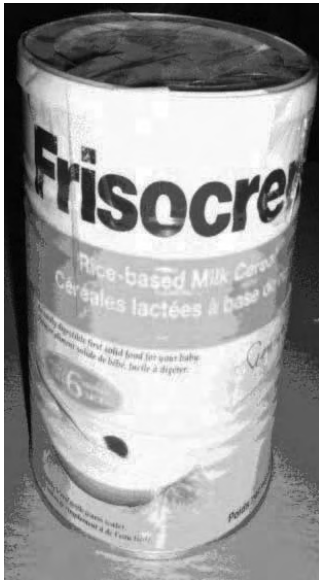
- Address on product:
**Eli Lilly Company
Limited Basingstoke,
England**
- **Colour changes on brown hologram** on exposure to light at different angles
- Date markings are **stated in words** i.e. **MAY 04 Jun 06**
- Registered by NAFDAC
NAFDAC No. 04-5196
Printed on the pack

- **Copied** the name and **address** on the original product
- **No** colour change on brown hologram
- Date markings are stated in **numbers** i.e. **M05 03 E 08 05**
- **Counterfeit** product **not registered** by NAFDAC
- **Has no** NAFDAC reg No.

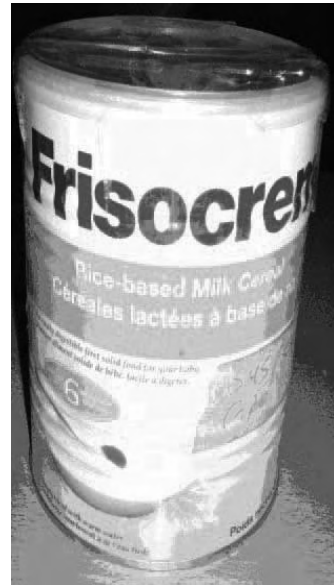
- No location address of Manufacturer
- Hologram **absent**
- Date markings are stated in **numbers**
- **Look-alike and soundalike** fake product **not registered** by NAFDAC.
- Has no NAFDAC reg No.

Figure 15: Sound-alike/Look-alike Counterfeit: *Cialis*

Original



Fake



- Has a white plastic cover.
- Date markings at the bottom of the container spans over three horizontal lines.
- Registered by NAFDAC
- **Rice based milk cereal - NAFDAC reg No. 01-0272 .**
- **Wheat based milk cereal – NAFDAC reg. No.01-7770**

- Has a transparent plastic cover.
- Date markings at the bottom of the container spans over two horizontal lines.
- Fake product not registered by NAFDAC.

Figure 16: Look-alike Counterfeit: *Frisocrem* Baby Food

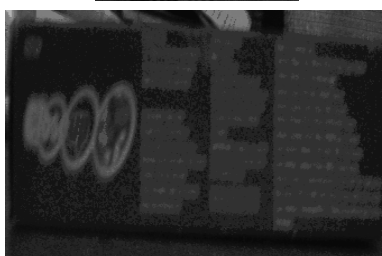
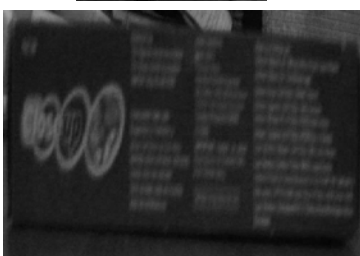
Original



Fake1



Fake 2



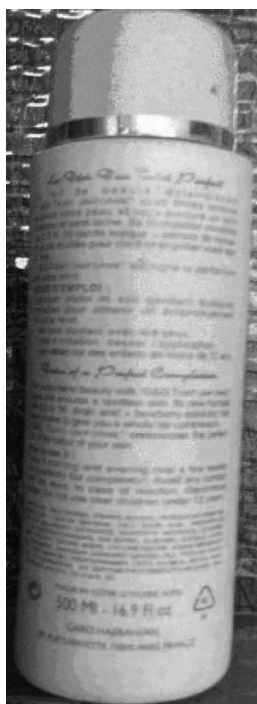
- Packet reflects seven UNILEVER address in various countries preceded by 'Made by' with a tick (" ") on UNILEVER Nig Plc, 1 Billing Way, Oregon, RC 113 as Manufacturer.
- Packet has FDI logo and has a white coloured UNILEVER logo.
- Customer care line on pack is 800-00-123 (national) written as the last number.
- Registered by NAFDAC
- NAFDAC reg No. 02-1539

- Packet reflects eleven (11) UNILEVER addresses in various countries preceded by 'Made by' with a tick (" ") on UNILEVER Nig Plc, 1 Billing Way, Oregon, as Manufacturer. (there is no RC113)
- -Packet has no FDI and UNILEVER logos.
- -Customer care line on pack is 802-00-123 (national) written as the last number.
- Copied NAFDAC reg No. of the genuine product.

- Packet reflects eleven (11) UNILEVER addresses in various countries preceded by 'Made for' with no tick on the particular country of manufacturer. There is no RC 113
- -Packet has no FDI logo but has a blue coloured UNILEVER logo.
- -Customer care line on pack is 802-00-123 (national) written as the last number.
- -Copied NAFDAC reg No. of the genuine product.

Figure 17: Sound-alike/Look-alike Counterfeit: *Close-Up Toothpaste*

Original



Fake



- -Made in Cote D Ivoire N.P.G Garo Hasbanian 139, Rue Lafayette 75010 Paris, France.
- The cover of the product has a silver lining.
- Has ingredients listed on the container.
- Registered by NAFDAC.
- NAFDAC reg No. 021813.

- Copied the address on the genuine product.
- The cover of the product has no silver lining.
- Has no ingredients listed on the container.
- Not registered by NAFDAC.

Figure 18: Look-alike Counterfeit: G & G Body Cream

Original



Fake



- Manufactured by PT Sayap Mas Utama Jakarta Timur 13910 Indonesia.
- Repackaged in Nigeria by Newone Industries (Nig) Ltd
- Satchets separated with tiny Dots.
- Has a pleasant fragrance.
- Back of sachet has a picture of “normal coloured hand” holding blue detergent.
- Registered by NAFDAC.
- NAFDAC reg No. 02-0576.

Manufactured For P.T Sayap Mas Utama **JI Tipar Cakung Kay, 5-7** Jakarta Timur 13910 Indonesia.

- Satchets separated with conspicuous **zig zag** lines.

- Has no fragrance.
- Back of sachet has a picture of “multicoloured hand” holding multicoloured detergent.
- Not registered by NAFDAC.

Figure 19: Look-alike Counterfeit: *Klin* Detergent

Evasion Techniques by Drug Counterfeiters

Falsification of Manifests

Importers and their clearing agents working with the counterfeiters collude with shipping lines to alter shipping manifests. Pharmaceutical products are falsely manifested as auto spare parts or other products. In some such cases, Single Goods Declaration (SGD) forms are wrongly declared with the sole aim of evading NAFDAC inspection. The SGD forms bear the name of products different from those being imported. They may also involve under-declaration of quantities of drugs imported. A few examples of the many such cases include the following:

On August 20, 2002, a 20-foot container of expired and unregistered cosmetic products, manifested as dictionaries and encyclopedias, was imported through Apapa Port.

On September 16, 2002, a 20-foot container of Micopen (fortified Procaine Penicillin) injection was imported from Hamburg, Germany. Futile attempts were made to clear the consignment manifested as cigarettes through the Apapa Port.

On June 13, 2003, our inspectors intercepted two 20-foot containers of canned beer consigned to Kirikiri Lighter Terminal (KLT), which were manifested as auto spare parts. Different copies of the same bill of lading bearing the same serial number showed auto spare parts on one container and canned beer on the other. The containers were intercepted after they had been released by the Nigerian Customs Service as non-NAFDAC items, and loaded onto trucks for transportation.

On August 13, 2003, an Ibadan-based physician imported assorted expired pharmaceutical products through the Murtala Muhammed International Airport and declared them as personal effects.

On January 4, 2006, at Apapa Port, Lagos, we seized a 20-foot container of fake pharmaceuticals valued at about ₦25 million (US\$217,391), manufactured in India. The contents were falsely declared as motor spare parts in the bill of lading. Drugs found in the container were Ibuprofen capsules (Paracetamol 325mg, Ibuprofen 200mg, Caffeine 40mg), Chlorpheniramine 4mg and Nildin (Phenylbutazone 100mg). Phenylbutazone is an anti-inflammatory analgesic, which was banned in Nigeria due to its life-threatening adverse effects such as bone marrow depression, hepatitis, renal failure, goitre and blood dyscrasia. Other drugs in the container were found to be fake and substandard.

Concealment

In order to conceal counterfeit drugs and other unregistered products, criminals hide them in unrelated cargo. Some counterfeit products are stashed in the inner parts of containers of other items like clothes, motor spare parts and household goods. We have made seizures of drugs concealed inside childrens' wear, men's clothes, duvets, shoes and DVD player cartons.

We have also encountered situations where desperate importers of unlawful medications smartly concealed Gentamycin injection and Seven Seas Cod Liver Oil under refrigerator compressors. Our officers intercepted this on February 5, 2002, at Tin Can Island Port. On May 14, 2002, two jumbo-sized bags containing Tramal capsules, a controlled narcotic analgesic, were imported from Pakistan through the Murtala Muhammed International Airport and carefully concealed, to give the impression that the bags contained dozens of T-shirts. In another case, 52 packages of Camoquin tablets, Ophthalidon tablets and other drugs were hidden in a mixture of machine spare parts and textiles and also imported through the Airport on February 10, 2003. They were intercepted on February 14, 2003, at Nigerian Aviation Handling Company (NAHCO) shed in Lagos.

On May 22, 2005, our officers at the Murtala Mohammed International Airport, Lagos intercepted several bags of different drugs and packaging materials, ingeniously wrapped in folds of baby T-shirts, shorts and other baby clothing. The concealed drugs included heat-sensitive drugs like insulin, anti-snake venom and rabies vaccine.

On March 3, 21, 28, 29 and April 1, 2006, we seized a number of jumbo-sized bags which concealed Visine eye drops, Artesunat tablets, Aldomet tablets, Halfan tablets, Proviron tablets and Ampiclox capsules, brought into Nigeria through Ethiopian and Lufthansa airlines, at the Murtala Mohammed International airport. The products were analysed at our laboratory and found to be substandard. The percentage of active ingredient in the Artesunat, an Artemisinin-based anti-malarial product was between 60 and 65 per cent, which was a far too low a specification for the active ingredient. The Aldomet, an anti-hypertensive drug, contained only 17 per cent of the active ingredient. The consignment of Artesunat was concealed in cartons containing men's jackets and trousers, while some were wrapped in duvets. The Visine eye drops were concealed in football boots, while the Halfan and Proviron tablets were hidden in children's clothes. In 2007, we intercepted fake Zinnat tablets (Cefuroxime), a powerful antibiotic manufactured by GlaxoSmithKline limited, perfectly concealed in cartons of DVD players (See Figures 20–25). The counterfeit Zinnat tablets, on analysis, were found to contain no active ingredient.



Figure 20: Drugs Concealed in Children's wear, Duvets, Shoes and Men's Clothes



Figure 21: Cross Section of Drugs Concealed in Baby Clothes



Figure 22: Drugs Concealed in Children's wear



Figure 23: Drugs Concealed in Duvets



Figure 24: Drugs Concealed in Men's Clothes



Figure 25: Zinnat (Cefuroxime Axetil Tablets, 250mg High-Potency Antibiotics), Product of GSK, Concealed in DVD Player Cartons

Release without Inspection

It is mandatory for all goods imported into Nigeria to be physically examined before release from the ports of entry. However, many consignments leave the ports without examination. Unlawful importers go to any length to avoid the inspection of the imports using several schemes, which include:

(a) Auctioning of NAFDAC Regulated Products as Overtime Cargo

The Nigerian Customs Service periodically auctions consignments abandoned at the ports, even when such products clearly fall within NAFDAC's regulatory control. However, due to oversight reasons, our officers are usually not part of the committees for the disposal of such abandoned or overtime cargoes. These expired or unwholesome products are eventually sold to the public. On one occasion, one of two 20-foot containers of abandoned pharmaceutical products being examined for auction by Customs at Lilypond Terminal, Ijora, Lagos, on July 18, 2003, was found to contain an unregistered drug product – Felvercap (Piroxican USP 20mg, a non steroidal anti-inflammatory agent), which had already gone moldy. Our officials put a stop to the auctioning and issued a 'Seizure' notice. NAFDAC wrote to the Comptroller-General of Customs concerning the auctioning of NAFDAC regulated products and the need to include NAFDAC officials in the committee on the disposal of overtime or abandoned cargoes at the ports (Appendices 19 and 20). The situation changed for the better after the intervention of the Comptroller-General. The committee began to invite NAFDAC for inspection and clearance before drugs and other regulated products were auctioned.

(b) Refusal to Submit Shipping Manifests to NAFDAC

In spite of the Presidential directive that all cargo manifests be made available to NAFDAC prior to the berthing of vessels, some shipping lines, did not comply with this directive. Poultry products declared as agricultural equipment were found in a Maersk Line vessel, MV.GEC Meadow, which berthed at Warri Port on January 11, 2003. NAFDAC is aware that a large proportion of evasions relating to false declarations of cargo occur with consignments carried by some shipping Lines.

(c) "Flying" Containers

"Flying" Containers is the popular name in the ports for containers that are never examined and are usually removed by a syndicate. With the connivance of some officials of the Nigerian Customs Service, they are loaded onto trucks and released at awkward times, especially at

night, without examination. The Special Squad of the Comptroller-General of Customs intercepted five 20-foot containers of unregistered Chop Boy Baking powder imported through Apapa Port on April 10, 2002. These containers were neither examined nor released by NAFDAC. A NAFDAC official found another 20-foot container of tainted supermarket items while it was being illegally removed from Apapa Port on June 10, 2003

(d) “Cut and Lock” Containers

In this category, the clearing agents load the containers into trucks, cut the seals and replace them with padlocks, to create a false impression that the containers have been examined. Our officials were usually misled into believing that the containers had already been properly examined by the relevant agencies. This “cut and lock” container system was employed on September 13, 2002, when our staff intercepted 2,642 cartons of 31 assorted fake pharmaceutical products, which had earlier been released and loaded into a truck at Apapa Port. Another example was the importation of Golden Harvest evaporated milk, which was about to expire. The shipment was intercepted on February 14, 2003, at the exit gate of Apapa Port by the Special Squad of the Comptroller-General of Customs. NAFDAC did not inspect the documents and there was no physical examination of the contents of the container.

(e) Illegal Transfers via Bonded Warehouses

When the ports are congested, goods might need to be transferred to bonded warehouses for inspection by the relevant agencies. In the process of this transfer, goods, which include counterfeit medicines and other substandard regulated products, are diverted to the importers’ warehouses. When we discovered that the bonded warehouses were being used as a conduit by importers and clearing agents to remove drugs and other regulated products from the ports, we resolved to start tracking the containers to their final destination. On one such occasion, a 40-foot container alleged to contain Sorbitol syrup and consigned to Unilever Nigeria was booked to be transferred from Kirikiri Lighter Terminal to Unilever’s bonded warehouse on October 11, 2002. We eventually discovered that the container never arrived at the bonded warehouse and that Unilever did not import those products. The container was found to contain fake pharmaceutical products imported by a Lagos-based pharmaceutical company.

(f) Smuggling

Importers who smuggle banned products into Nigeria sometimes use ports of neighbouring countries in the West African sub-region as transit ports. Transited imports are then smuggled into the country via land borders. The most popular border is Seme, between Nigeria and the Republic of Benin. Most of the fake and unregistered products that come into Nigeria come via Seme border presumably with the support and connivance of some Beninise officials. On April 20, 2003, the Western Marine Command of the Nigerian Customs Service, at Ibafo, Lagos, intercepted 333 cartons of various pharmaceutical products as they were being smuggled into Nigeria.

Discriminatory Export Regulation by Exporting Countries

Discriminatory regulation of drugs meant for export has compromised the quality of drugs moving in international commerce. In some countries, drugs meant for export are not subjected to the same stringent regulations as those for internal use in the country of manufacture. A typical example, is poorly blister-packaged Paracetamol sachets labelled “Not for Use in Southeast Asia” found in one of our numerous seizures. This practice informed NAFDAC’s decision to prohibit the importation of products labelled “For Export Only”. Poor regulation of exports from manufacturing countries exposes importing countries with weak regulations to dumping of fake pharmaceutical products. This is critical since about 60 per cent of drugs in Nigeria are imported. Most of the counterfeit medicines in circulation in Nigeria come from India and China.

Lack of Awareness

Drug counterfeiters succeeded in Nigeria for over three decades because of the lack of awareness, which was made worse by the culture of silence that enshrouded the issue of counterfeiting drugs and other regulated products. People died inexplicably after the right diagnosis and correct medication were given without a link being made between the deaths and the counterfeit medicines. It was because of this lack of awareness that my family failed to look for another source of insulin for my late sister Vivian. NAFDAC and its roles did not ring a bell in the ears of many Nigerians then. There was also general ignorance about the need for Expiry/“Best Before” dates and the right storage conditions for drugs and other health sensitive products.

Lack of Political Will

A number of measures necessary for effective drug regulation by the national drug regulatory authorities require the political will of government for successful implementation. In 2002, the Nigerian Government banned the importation of drugs through land borders and designated two airports and two seaports for drug importation. Before this restriction, drugs were imported through all ports of entry into Nigeria and this made control almost impossible, because previous governments lacked the political will to do what former President Obasanjo did.

Unfavourable Government Policies

The Nigerian Port Reforms Policy of 1996, which denied NAFDAC access to the ports of entry, is a typical example of an unfavourable government policy. NAFDAC was asked to leave the ports because of the unbridled level of corruption. This led to the incessant influx of fake/counterfeit versions of regulated products into the country. This situation existed until October 2001, when President Obasanjo acceded to NAFDAC's request for our officials to return to the ports.

Political Instability

Change in government policies caused by frequent changes of government, does not allow for sustainability of policies geared towards creating an effective regulatory environment. To justify the need for change, every new government prefers to design its own policies and programmes, discarding those of their predecessors. This was especially rampant during the military era. The years of uninterrupted democratic rule in Nigeria engendered a seamless operating regulatory environment.

Inadequate Cooperation among Government Agencies

Inadequate cooperation among government agencies and organisations like NAFDAC, Customs, Police, the National Drug Law Enforcement Agency (NDLEA), the Standards Organisation of Nigeria (SON), clearing agents and shipping lines, create fertile ground for counterfeiters to escape detection, arrest and sanctions. In the past, stop notices issued by NAFDAC to some of these agencies at the ports were ignored or not acted upon, resulting in the release of products suspected to be fake, substandard or unwholesome.

Chaotic Drug Distribution System

An important factor militating against effective drug regulation is the chaotic drug distribution system. For many decades, drugs have been marketed like any other commodity of trade in Nigeria. Most Nigerians patronise these illegal drug markets, including the hawkers who openly sell drugs on the streets and on board commercial buses and ferries. These drug markets flourish all over the country despite their illegality. Our efforts to create an orderly drug distribution system, which would phase out the existing chaotic system, suffered a grave setback. Ironically, pharmacists, who were supposed to be the major beneficiaries of an orderly drug distribution system, opposed it.

Demand Exceeding Supply

Another factor that encourages drug counterfeiting is the excessive demand for drugs in the face of scarcity. Naturally, prices rise when demand is greater than supply. Increased demand when drugs are in short supply is an incentive for counterfeiting. Fast-moving products, which are not regularly supplied to consumers by genuine manufacturers, are often prone to parallel importation and faking.

Irrational Drug Use

Self-medication, which is a common practice in Nigeria, encouraged large consumption of drugs and provided a good market for drug counterfeiters. In addition, some health professionals have so much deviated from their core areas of competence, that we now have dispensing doctors, prescribing nurses and diagnosing pharmacists. Purchase of all ethical drugs without prescription, which was the general practice in Nigeria, promoted the irrational use of drugs and saw many drug counterfeiters happily smiling on their way to the bank.

Poor Database on Health-Related Activities

Another factor that encouraged faking of medicines and other regulated products in Nigeria is poor or non-existent record keeping of health-related activities in various health establishments. There is actually no documentation or database on drugs used previously and experiences gained from their use. The general attitude of prescribing without adequate laboratory tests and proper diagnosis leads to trial by error therapies, which have the tendency of covering up the effects of the use of counterfeit medicines. In this trial by error therapy, a doctor who prescribes Ampiclox quickly switches over to Septrin or Erythromycin, or other antibiotics, without finding out why the patient did not respond to the first drug. The same

story goes for a quick switch from Paracetamol to another analgesic, without finding out why that particular brand of Paracetamol did not work, especially if it happened repeatedly. Switching very quickly from one medicine to the other without finding out why the previous one failed and non-reporting of these experiences exacerbates the fake drug saga. We always stress in our meetings with relevant stakeholders that such treatment failures should be reported to NAFDAC, so that we can track down counterfeit medicines right from the hospitals, to their distributors, importers and manufacturers.

CHAPTER 14

INSTITUTIONALISING THE CHANGE

When the new management came on board, the food and drug regulatory environment in Nigeria was characterised by total chaos and confusion. There were no procedures and guidelines for the performance of our duties, decisions were subjective, and members of staff did not have a clear-cut understanding of their roles. These lapses and inefficiencies bred corruption and ineptitude in the organisation. In order to build a vibrant and sustainable institution, we needed to develop guidelines and Standard Operating Procedures (SOPs), to ensure uniformity in executing all our regulatory functions. Guidelines and SOPs now exist for most NAFDAC activities such as Good Manufacturing Practice (GMP) Inspections, Import and Export Inspections, Sample Collection, Laboratory Analysis, Strict Registration Practices, Fines and other Penalties for Violations, Consumer Complaints, Advertisement Control, Development of Regulations and Post Marketing Surveillance (PMS). In addition to ensuring uniformity in our activities, the Guidelines and SOPs also help to guarantee continuity in our processes. These Guidelines and SOPs are dynamic, evolving with the changes in our various regulatory activities and each time we make changes, we communicate them to the public through print and electronic media.

When counterfeit medicines are found in a shop, the standardised method for conducting investigations is as follows:

1. Obtain receipt of purchase of the counterfeit medicines from the seller/retailer.
2. Use the purchase receipt to trace the distributor.
3. Obtain a receipt from the distributor and use it to trace the importer.
4. Trace the manufacturer and the manufacturing site from the importer or through the import documents.
5. Ban the manufacturer of the fake drug from exporting drugs to Nigeria.
6. In the process of these investigations, each arrested person is kept in detention for the maximum length of time permitted by the law of the land.

7. The retailers, from whom the process of investigation started, are usually released, as they always claim ignorance of the fact that the drugs were fake. This is understandable considering that most people, including original brand owners, find it difficult to tell the difference between the original brand and the counterfeits. However, the retailer is still made to pay a fine of ₦100,000 (US\$870), in addition to the closure of the shop for at least one week.
8. The distributor gets the same treatment as the retailer. Their warehouses are shut down, as a way of making them more vigilant in their future purchases of medicines.
9. The importer, who cannot possibly claim ignorance, is not only arrested, but is also prosecuted.

To remove counterfeit medicines from circulation, samples of the counterfeit medicines and samples of the genuine drugs are distributed to all our state offices nationwide. With the fake and genuine samples placed side by side, our officers are able to comb the markets and shops across the country, mopping up the fake ones from circulation for public destruction. Retailers who are found to be in possession of the counterfeit medicines are interrogated. The interrogation generally produces information that could lead to the identification of the importers and manufacturers of the counterfeit medicines. This procedure also applies to food, cosmetics and other regulated products.

SOPs for imported unregistered drugs

In the first few years of the new management, samples of unregistered drugs were collected and analysed in our laboratory. When a sample passed laboratory analysis, the importers were made to pay for the cost of the laboratory analysis and pay a fine for importing unregistered drugs before the drugs were released to them. This procedure was in place for over five years, until we observed that the influx of unregistered drugs was not going down as fast as we wanted. As time went on, the importers continued to import unregistered drugs, because they found it easier to pay the fine. We therefore changed our procedure to outright seizure and destruction, without the option of a fine, for all imported unregistered drugs. For drugs that fail laboratory analysis, in addition to destruction, the importer is prosecuted, with no option of a fine. We did, however, retain the old guidelines for food and cosmetics. By 2008, we found that unregistered imported food products were flooding the markets, undeterred by the old guidelines. We therefore changed our SOPs for food and cosmetics, to make it more difficult for people to get away with importing unregistered food

and cosmetics products. In our new SOP, if the imported product fails laboratory analysis, the importer forfeits the product and pays the cost of the destruction. However, if the product passes analysis, the importer will be made to pay a fine of ₦5,000,000 (US\$43,478) for a 40-ft container, ₦3,000,000 (US\$26,086) for a 20-ft container or ₦2,000,000 (US\$17,391) for half of a 20-ft container or less. If the importer fails to make this payment, the products will be seized and transferred to the Nigerian Customs Service for auction. The heavy fines made the importation of unregistered food and cosmetics most unprofitable.

The minimum standards required for products' certification are stated in our SOPs, which are adapted from international standards. We regularly monitor local manufacturers. When any of them is found to violate our minimum standard requirements in any section of their production facilities, especially if this results in substandard or contaminated products, the factory is shut down. The factory is issued with compliance directives, which must be fully met, in addition to the payment of an administrative fine, before it is re-opened. However, if at the time of inspection, we find lapses in any aspect of the company's manufacturing procedures, but find that their products are compliant with the minimum required standards, we issue the factory with a compliance directive and charge them a minimum administrative fine. If all the compliance directives are not met within a specified time, the factory is shut down. A maximum administrative fine of ₦5 million (US\$43,478) is charged in lieu of prosecution for any factory found to be willfully producing substandard regulated products.

A cosmetics factory found to be adding Mercury, Hydroquinone over 2 per cent or any other banned substance to its products is closed down and the same sanctions are administered as for a defaulting drug manufacturer.

For food, when a factory is found to produce and sell non-iodised salt, it is closed down and made to pay a fine of ₦100,000 (US\$879). Bakeries that are confirmed as adding Potassium bromate to bread are fined ₦20,000 (US\$174) and shut down when caught a second time. In 2002, our initial procedure was to test bread from bakeries and once we found any containing bromate, we confiscated and destroyed them publicly. Thereafter, we issued a new guideline requiring that any baker found using bromate in bread would be prosecuted. We prosecuted some bakery owners, but unfortunately, the cases are still pending. When we realised how slow the court system was, we changed our procedure. In the new SOP that came into effect in June 2008, defaulting bakeries are shut down and charged a fine of ₦50,000 (US\$434).

Table 7: Approved Administrative Fines1. Distribution / Sales Outlets

Type Of Violation	Administrative Fine(₦)
i. Sale of unregistered products	100,000 – US\$ 870
ii. Sale of expired/banned products iii. Improper labelling	200,000 – US\$1,740 50,000 – US\$ 435
iv. Alteration of expiry dates	200,000 – US\$1,740
v. Sale of products labelled in foreign languages without English language translation	100,000 – US\$ 870
vi. Sale of banned imported foods	50,000 – US\$ 435
vii. Sale of products containing banned additives and sweeteners	100,000 – US\$ 870
viii. Sale of cosmetics containing banned substances	100,000 – US\$ 870
Sale of fake, substandard and unwholesome food products	
ix. Sale of fake, substandard and unwholesome food products	100,000 – US\$ 870

2 Patent and Proprietary Medicines Vendors:

Type Of Violation	Administrative Fine(₦)
i. Sale and distribution of fake, expired or banned products	20,000 – US\$174
ii. Sale of unregistered products	20,000 – US\$ 174
iii. Alteration of expiry date	30,000 – US\$ 261

3. Manufacturing Establishments:

Type Of Violation	Administrative Fine(₦)
i. Delay in renewal of licence	50,000 – US\$ 435
ii. Unsatisfactory GMP report post-registration	50,000 – US\$ 435
iii. Introduction of new pack sizes without permission or authority	50,000 – US\$ 435
iv. Non-compliance with labelling regulations v.	20,000 – US\$ 174
Usage of wrong packaging materials	20,000 – US\$ 174
vi. Illegal contract manufacture	100,000 – US\$ 870
vii. Producing without Production Manager on Premises	50,000 – US\$ 435
viii. Change of location without approval ix.	50,000 – US\$ 435
Manufacture of unregistered products:	
(a) Small scale	20,000 – US\$ 174
(b) Medium scale	50,000 – US\$ 435
(c) Large scale	200,000 – US\$1,740
Use of fake NAFDAC number	250,000 – US\$2,174

4 Bakeries:

Type Of Violation	Administrative Fine(₦)
Use of bromate as bread improver and use of other banned food additives	50,000 – US\$435

5 Pharmaceutical Premises:

Type Of Violation	Administrative Fine(₦)
i. Sale and distribution of fake, expired and banned products	200,000 – US\$ 1,740
ii. Sale of unregistered products	100,000 – US\$ 870
iii. Manufacture and distribution of unregistered pharmaceutical products	200,000 – US\$1,740
iv. Alteration of expiry date	1300,000 – US\$2,610
v. Manufacture of fake pharmaceutical products	300,000 – US\$2,610

We also developed SOPs for the procurement of various products required in our laboratories. The contents and qualities of regulated products are determined through laboratory analysis and therefore, critical regulatory decisions are based on the results of these tests. I discovered that there was no systematic approach to purchasing the reagents and chemicals needed in our laboratories. Laboratory reagents and chemicals were randomly purchased from just any source. Consequently, substandard and adulterated reagents and chemicals were supplied which led to inconsistent and unreliable test results. The integrity of our analysis, upon which critical decisions are based, became questionable. There were also shortages of laboratory supplies and this caused delays in the entire regulatory process. We found this totally unacceptable. We needed our laboratories to be such that any test result released could not be successfully contested anywhere in the world. I saw these laboratories and their output as crucial to our success in the war against counterfeit medicines and unwholesome food. To ensure excellent quality and uninterrupted supply of reagents and chemicals to the laboratories, we entered into a direct purchasing agreement with the Merck Group. This agreement was for five years of uninterrupted supply of the various reagents and chemicals needed for the smooth, efficient and effective operation of our laboratories. The agreement also included training of our staff on supervisory services in the laboratories, proper handling of chemicals, new analytical procedures and Good Laboratory Practice. This has ensured the integrity of our laboratory test results and has

enabled our staff to perform their various functions more efficiently, thereby assisting in restoring public confidence in NAFDAC.

SOPs for Various Regulatory Activities

We have developed SOPs for carrying out various regulatory activities. These include;

- Generating, approving, using, maintaining and controlling of Standard Operating Procedures intended for use within NAFDAC.
- Drafting and obtaining gazetted Regulations.
- Searching for, collating and arranging information for preparing the draft of a new or revised Regulation.
- Counselling a client for the purpose of regulated product registration.
- Processing and issuance of GMP certificate for requesting manufacturers.
- Inspecting drug manufacturing establishments to ascertain that the factory is suitable for production of pharmaceuticals for which the client is applying.
- Processing of NAFDAC Recognition Letter for companies intending to manufacture drug products and notification of other regulatory authorities.
- Developing Letter of Recommendation to Registration and Regulatory Affairs (R&R) Directorate for manufacturers intending to register drug products.
- Processing of NAFDAC permit issued to client intending to import drug samples meant for registration purposes.
- Receiving and handling imported drug samples for laboratory analysis while maintaining acceptable identity standards.
- Vetting of imported drug product samples submitted for registration and ensuring that the samples meet required standards in compliance with the regulation.
- Presenting submitted drug samples for registration approval.
- Changing of pharmaceutical product name as requested by the client.
- Processing change of drug source, or manufacturing facility for an intending client that imports such product.
- Renewing already registered drug products to ensure that the relevant NAFDAC requirements are met by the manufacturer following initial registration approval.

- Processing service drugs import permit for community pharmacies.
- Processing service drugs import permit for multinational pharmaceutical companies.
- Treating enquiries on food by stakeholders.
- Vetting of Regulated Food Products to ensure products' compliance with NAFDAC labelling requirements.
- Preparing for NAFDAC production inspection of processed food and packaged water manufacturing establishments.
- Inspecting processed food establishments to ascertain that products are produced in line with required GMP and other regulatory standards.
- Handling and sampling of food/water samples during production inspection for analytical purposes.
- Handling and sampling of processed food/packaged water samples during production inspection for analytical purposes.
- Inspecting packaged water establishments to ascertain that packaged water is produced in line with required GMP and other regulatory standards.
- Certifying semi-processed/processed food commodities for export to ensure that only wholesome products of acceptable quality are exported from Nigeria.
- Handling and investigating Alert Notifications on food commodities exported from Nigeria in order to determine the source of errors and prevent re-occurrence.
- Vetting inventory of items submitted for Global Listing of Supermarket Items (GLSI) by supermarket/fast-food/restaurant/hotel and related operators.
- Requesting NAFDAC Establishment Inspection Directorate to conduct inspection of GLSI scheme premises.
- Vetting and ensuring the completeness of documents submitted for GLSI by supermarket/fast-food/restaurant/hotel operators.
- Preparing and issuing of Compliance Directive to the supermarket/fast-food/restaurant/hotel operators in the GLSI scheme.
- Making sure that supermarket/fast-food/restaurant/hotel operators in the GLSI scheme comply fully with the issued Compliance Directive.

- Receiving corrected inventory of items from supermarket/fast-food/restaurant/hotel operators in the GLSI scheme that have fully complied with the issued Compliance Directive.
- Writing the memo forwarding to the Director (Ports Inspection Directorate) the approved inventory of items of supermarket/fast-food/restaurant/hotel operators in the GLSI scheme.
- Collecting Acknowledgement Form that has been endorsed by the Director (R&R) from the Assistant Chief Regulatory Officer (ACRO) (R&R) for supermarket/fast-food/restaurant/hotel operators in the GLSI scheme.
- Giving Acknowledgement Form that has been endorsed by the Director (R&R) to supermarket/fast-food restaurant/hotel operators that have GLSI completed.
- Collecting the memo to the Director (Ports Inspection Directorate) that has been endorsed by the Director (R&R) from ACRO (R&R) for onward transmission to the Directorate.
- Changing of company representative within a GLSI application process scheme.
- Preparing GLSI certificates.
- Issuing of registration certificates to authorised applicants.
- Issuing of pre-release stamp on Single Good Declaration (SGD) forms/airway bills/auction papers of imported regulated products.
- Transferring the first stamp from one Single Good Declaration form to another or stamping additional Single Good Declaration form to ensure that consignments landing in ports different from originally designated ports or consignments that short-landed (i.e. contained less than on the manifest) can be cleared.
- Issuance of second stamp for the final release of imported consignments of regulated products to the importer.
- Assessing imported consignments of regulated products for the purposes of ensuring payment of appropriate NAFDAC port charges.
- Cancelling of “Query” or “Put on hold” stamp placed on SGD forms/airway bills/auction papers of imported regulated products.

- Preparing Acknowledgement Forms for supermarket/fast-food/restaurant/hotel operators in the GLSI scheme that have completed the process.
- Handling unsatisfactory laboratory reports of samples of imported regulated products received from laboratories to ensure that only products that meet the Agency's specification go into circulation.
- Ensuring that appropriate sanctions are applied to the importers of all offending regulated products and /or the products.
- Placing of "Hold" label on offending imported regulated product(s) in order to prevent their circulation to the public.
- Removing of "Hold" label on offending imported regulated product(s) in order to release them to the importer.
- Inspecting and sampling of imported regulated products at the port of entry for laboratory analysis in order to ascertain the quality.
- Inspecting and sampling of imported regulated products at the importer's warehouse, for laboratory analysis in order to ascertain the quality.
- Inspecting refrigerated containers carrying regulated products (frozen fish, vegetables, cheese, etc.) in order to ascertain the temperature of the storage and ascertain the wholesomeness of the product.
- Storing retention samples of drugs, food, cosmetics, medical devices and agrochemicals imported through ports and land borders in order to have access to a reference sample of the product sent to the laboratory.
- Handling and transportation of samples of regulated products from the ports to the Ports Inspection Directorate (PID) stores in order to preserve the integrity of the product.
- Evacuating seized consignments of offending products thereby preventing such products from going into circulation.
- Responding to alerts on counterfeiting and blacklisting of erring companies.
- Entering the particulars of NAFDAC approved products into NARPAD.
- Appointing new employees.
- Documenting new employees.

- Promoting members of staff.

We also have SOPs for all our laboratory activities. These include;

- Distribution of samples to analysts.
- Determination of total ash.
- Determination of uniformity of weight.
- Acute toxicity test for herbal medicines.
- Anaesthetic effect of Halothane on rats.
- Biological assay of Oxytocin.
- Flow rate for medical devices.
- Determination of sleeping time of Diazepam.
- Biological assay of insulin.
- Receipt of sample into the pharmacology lab.
- Determination of Methylsalicylate in ointments using gas chromatograph.
- Preparation of samples for atomic absorption spectrophotometer.
- Determination of Artemether content.
- Determination of Lamivudine and Stavudine and Nevirapine Tablets' content, and other combinations.
- Determination of Paracetamol content.
- Testing of Glibenclamide tablets.
- Testing of Chloroquine phosphate injection.
- Quantification of the total solid matter of alcoholic beverages.
- Determination of total acidity in alcoholic beverages.
- Determination of alcohol content as per cent ethanol in samples of regulated products.
- Determination of Original Gravity (OG) of Wort in beer.
- Determination of the specific gravity of alcoholic beverages.

- Determination of carbon dioxide in carbonated wine and beer.
- Quantification of total sugar and sucrose contents in alcoholic beverages.
- Estimation of the total number of aerobic mesophilic bacteria in a particular food sample.
- Qualitative detection of *E. coli* 0157:h7 in food samples.
- Detection of *Pseudomonas aeruginosa* in water.
- Determination of organochlorine and organophosphate pesticide residue in spices.
- Micro-determination of organochlorine and organophosphate residues in milk and milk products.
- Screening of food samples for gamma radioactive isotopes (¹³⁴CS and ¹³⁷CS) using scalar timer ST7.
- Determination of Total Aflatoxins in food samples.

Typical examples of NAFDAC SOPs are shown in Appendices 21a–21e.

INSTITUTIONALISING CHANGE THROUGH PRODUCT REGISTRATION

Our registration process entails GMP inspection of production factories both within and outside the country. The Agency ensures total adherence to all other SOPs lined up for product registration, which includes laboratory analysis, vetting of product labels and other forms of documentation. The information from all these activities is considered by the Food, Drug and Related Products Registration Committee (FDRPRC). This committee is an approval committee and draws its membership from the Legal Unit in the Director General's Office and all the technical Directorates within NAFDAC. The registration process ends with the approval of the product and issuance of a NAFDAC Registration number, to be affixed on the product package, as a mark of NAFDAC's approval of the product's quality and safety. Importers and their foreign partners were required to affix NAFDAC registration numbers on both the inner and outer packaging of their products meant for importation, sale or use in Nigeria.

In 2002, we reviewed our products registration guidelines, whereby a deadline for registration was set for imported products, after which it became illegal to sell unregistered products.

Our first deadline for mandatory registration and the affixing of a NAFDAC registration number was January 1, 2003. This was extended to July 1, 2003 to allow the stakeholders sufficient time to comply with the directive. Several professional groups including journalists appealed for a further extension. After consultations with stakeholders, the deadline was further extended to January 2004. To this effect, public notices were placed in the print and electronic media. We urged Nigerians to reject any regulated product, which did not bear a NAFDAC registration number.

To further curtail dumping of substandard products and encourage our local manufacturers who have adequate production capacities for Over the counter (OTC) drugs, our Governing Council on October 3, 2003, approved limits on the registration of different brands of imported OTC drugs. It is important to note that this guideline did not in any way, cancel the marketing authorisation of already registered imported OTC drugs automatically. Using Paracetamol as an example, there were 65 registered brands of Paracetamol tablets as against the ceiling for 70 brands. In addition, product registration is renewable every five years and is automatically cancelled if there is no evidence of renewal commencement three months after the expiration of the previous registration. Late renewal attracts a fine. Imported drugs that are not classified as orphan drugs could be registered and renewed only once. Therefore, non-orphan drugs can be marketed in Nigeria for a maximum of 10 years, after which the medicine importer must commence production of such drugs in Nigeria.

We have step-by-step SOPs for strict inspection of imported products at the ports to ensure that only registered products are allowed into the country.

There are SOPs for monitoring and control of product advertisements to ensure that the claims are not misleading, exaggerated or false.

Furthermore, on April 19, 2005, the Federal Government of Nigeria banned the importation of 17 medicaments and other products. Consequently, a 16-member Inter-Directorate Committee was formed to deliberate on and interpret any grey areas in the Import Prohibition List. The Committee established that some products should be exempted from the list. These included vitamins, multivitamins and formulations for specified disease states and physiological conditions such as HIV/AIDS, complicated diabetes, cerebrovascular system conditions, pregnancy, menopause, neoplastic diseases and terminal illnesses. In addition to these exemptions, the Committee recommended that local manufacturers of generic products

should establish that their products are bioequivalent to those of the innovators and reiterated that real time stability studies of these products were necessary.

While most imported drugs vary in duty rates paid, antimalarials such as Artemisinin, Lumefantrine and Amodiaquine and antiretroviral drugs (ARVs) for HIV/AIDS, attract no duties. Other details are available on NAFDAC's website –www.nafdac.gov.ng.

Our guidelines are comprehensive and have improved communication between our stakeholders and the Agency. Our SOPs have reduced decision-making time and improved the performance of our regulatory functions. These SOPs and guidelines are dynamic. They are the surest ways of institutionalising our programmes and processes in order to ensure that our successes do not depend on any individual or group. We recognise that building an institution is critical in sustaining our successes.

CHAPTER 15

FOCUSING ON FOOD

Ensuring the safety and quality of food products in Nigeria is one of the key responsibilities of NAFDAC. The Agency works towards the fulfillment of this mandate through the regulation and control of local production, importation, exportation, manufacture, storage, advertisement and distribution of food products. Ensuring national food safety for a country as vast in land mass (924,000km²) and population (150 million people) as Nigeria is a challenging task. It is even more challenging given that Nigeria is still a developing country with a large proportion of the population still illiterate. We work to achieve our mandate through immediate, medium- and long-term strategies.

Immediate Strategies

These are plans that were introduced between 2001 and 2003 and have become standard practices in NAFDAC. They include:

Registration of Food Products

Manufactured or processed food products for distribution and consumption in Nigeria, whether locally produced or imported must first be registered in Nigeria. Before food manufactured locally is registered, NAFDAC inspects the production factory to ensure that it is GMP compliant. The food is screened in the laboratory to ensure that it is safe and of good quality. We ensure that what is stated on the label is what is contained in the product and that the product does not contain any banned or extraneous material. As in the case for drugs, we carry out routine surveillance of food production factories in Nigeria to ensure continued compliance with international standards. At ports of entry, we carry out random sampling of food products to ensure continued compliance with stipulated standards. Food production factories outside the country are also blacklisted if they are found to be producing unwholesome food, or if they seriously contravene our guidelines. After the global Melamine crisis of 2008 (when tainted milk resulted in a number of deaths), NAFDAC issued new guidelines requiring that all milk products from India or China be re-certified by our independent analysts in those countries before they are exported to Nigeria.

Development of Regulations and Registration Processes: Guidelines, SOPs and Regulations

NAFDAC developed Guidelines, SOPs and Regulations for food and food products. The food SOPs aid us in ensuring uniformity and continuity in the assessment and certification of food products. The food regulations cover such categories as Sugar and Sugar Products Regulations, Pet Foods Regulations, Pre-packaged Food Labelling Regulations, Food Additives Regulations, Food Products (Advertisements) Regulations, Food Grade (Table or Cooking) Salt Regulations, Food Fortification With Vitamin A Regulations, Processed Food Registration Regulations, Milk and Dairy Products Regulations, Marketing of Infant and Young Children's Food and Other Designated Products (Registration, Sales, etc.) Regulations.

Staff Training, Development and Empowerment of Stakeholders

We identified the need to sensitise, educate and empower the various stakeholders to better understand NAFDAC's food regulatory procedures and guidance, in order to foster a culture of compliance. We organised training for all stakeholders involved in food production. Notable among them are fast-food restaurants, flour millers and bakers, farmers and grain merchants, producers of salt, sugar and vegetable oil, and producers of beverages (alcoholic and non-alcoholic), water and juices. In 2002, the Agency organised a workshop to sensitise the food and beverage industry on a new directive that required them to add expiry dates to food packaging and indicate the percentage of alcohol content in alcoholic beverages. We thereafter wrote to all alcoholic beverage manufacturers to effect this directive (Appendix 22) and published a public alert notice (Appendix 23).

We benefited from the support of major international bodies such as the World Health Organisation (WHO), Food and Agriculture Organization (FAO), Standards and Trade Development Facility (STDF), United Nations Children's Fund (UNICEF), United States Agency for International Development (USAID), International Atomic Energy Agency (IAEA) and World Trade Organization (WTO). These organisations provided opportunities for capacity building through the training and development of NAFDAC staff, both within and outside Nigeria.

Medium-Term Strategies

The medium-term plans, which began in 2003 and ran through to 2007, were developed to enable us to achieve a paradigm shift from supervisory regulation to self-regulation by the industry. They include programmes that would engender cooperation and collaboration amongst various arms of government involved in food safety and hygienic practices. They also include development of tools to enable consumers to become foot soldiers for NAFDAC in all the nooks and crannies of the country. Some of these tools are:

Advisory Tools and Publications

We identified the need for handy informative technical booklets, which could be used for the purpose of disseminating technical information, for both the industry and regulatory officers. To address this need, we embarked on the publication of various informative booklets such as the NAFDAC Consumer Safety Bulletin, NAFDAC Guidelines for Food Hygienic Practices and NAFDAC Handbook on Food Additives. Some of these publications also contain advisory information for both the regulators and the regulated industries.

Advanced Regulatory Protocols

Based on the need for us to improve our food regulation procedures in line with modern trends, there was the need to shift towards more advanced scientific inspection and control of food products. This was achieved through the adoption of established international protocols, systems and tools as provided by international bodies such as the WHO, FAO, Codex Alimentarius Commission, Organisation International Des'Epizooties (OIE) and International Plant Protection Commission (IPPC). To implement this strategy, we needed to develop the requisite skills and capacity within our organisation. Consequently, from 2003 to 2006, many of our staff in the food division were trained in the latest food safety management systems and protocols, which include cGMP, HACCP and Risk Assessment.

Long-Term Strategies

A broad-based approach has been identified as a viable, strategic approach to ensuring the safety of national food supply. In this regard, we developed plans to ensure sustainable cooperation and collaboration among all relevant government ministries, departments and agencies, research institutes and the food industries, in accordance with our role as stipulated in the Nigerian National Policy on Food Safety. The strategic plans include:

Food Hygienic Practices Training

The regulatory instrument for the introduction and implementation of this broad-based approach to food safety in Nigeria is our Guidelines on Food Hygienic Practices, which is a good reference material for Train the Trainers workshops on food and agricultural products' handling. The guidelines promote compliance with SPS requirements, which ensures safe food practices for both local and international trade.

Establishment of National Food Risk Analysis Centre

In 2001, we participated in a national workshop on Food Security and Food Safety at the International Institute for Tropical Agriculture (IITA) in Ibadan, Nigeria. Since then, we have judiciously utilised every opportunity available to us to build our capacity on SPS matters. We have trained relevant staff members on risk assessment and have presented papers on it at several national and international fora. From our vantage position as lead agency for food safety in Nigeria, we realised that institutionalising Risk Assessment was the right way to go. We therefore presented a memo to the National Council on Health for the establishment of a National Food Risk Analysis Centre (NFRAC) in NAFDAC and it was approved. Since then, we have moved speedily towards the inauguration of the NFRAC. The Director General of NAFDAC is the Chairperson for the NFRAC, which is an inter-ministerial and inter-sectoral centre for the relevant government ministries, departments and agencies, the industry and academia. The NFRAC has risk analysis responsibilities for food safety. The Centre has developed a Memorandum of Understanding, which serves as a basis for collaboration amongst member organisations.

The objectives of the Centre include enhancing communication and coordination on scientific data on food safety in Nigeria. It also promotes the conduct of scientific research and development of a national database on food safety, to assist the regulatory and enforcement agencies in fulfilling their specific food-safety risk management mandates.

The goals of the Centre include institutionalising risk analysis on food safety risk assessment, animal health risk assessment and plant health risk assessment in Nigeria. It will also enable the development and maintenance of a central database on exposure of consumers to contaminants in food through diets, pests and diseases in primary agricultural products, which are basic raw materials for food production and export.

The Centre will identify critical research needs in primary agricultural products for adequate food safety and risk assessment work. It is envisaged that the Centre will also improve

efforts at conducting research work related to risk assessment by encouraging multi-disciplinary efforts, offering advice and encouraging researches in food safety related departments at higher institutions and creating the required synergy for Nigeria to become a major player in the international market.

Other goals of the NFRAC include facilitating knowledge acquisition in food safety analysis and encouraging application of data on food risk analysis in Nigeria. It will also promote identification, cataloguing and publishing of risk assessment reports, methods, models and data sets. The Centre will provide advice and serve as a technical resource for its member organisations, thereby facilitating trade and reducing Technical Barriers to Trade (TBT) in food and agricultural products.

All facets of these strategic plans are already in operation and at different stages of execution. Some of them have already become engraved as norms, while others, especially the long-term strategies, are in progress.

Obligatory International/National Roles

NAFDAC represents the country at various meetings of international organisations. Membership and/or participation at these international fora gave rise to certain roles and functions, which we perform in fulfilment of our international obligations as the National Food Safety Authority (NFSA) in Nigeria. These roles are:

International Roles

- i. Enquiry Point of the World Trade Organization Sanitary and Phytosanitary (WTO/SPS) Measures

NAFDAC has been the WTO/SPS Enquiry Point for Nigeria since the late 1990s. We liaise with the Federal Ministry of Commerce & Industry, which is the WTO Notification Authority for Nigeria, to carry out the food safety and quality related activities of the SPS Committee of the WTO. To do this effectively, an SPS desk was established in our Regulatory Affairs Division. The SPS Enquiry Point functions include responding to enquiries on standards, regulations, guidelines and contact persons that would aid international trade in food, animal and plant products. The Nigerian SPS Enquiry Point's website (www.spsenquirypointnigeria.net) was created to assist in this regard and is manned by NAFDAC personnel. The website was developed to:

- * fulfil the responsibility of NAFDAC as the Enquiry Point for SPS issues in Nigeria;

- * facilitate international trade;
- create electronic access between the entrepreneurs in food and agricultural products and the relevant government officials or bodies responsible for specific SPS matters affecting their products;
- * be an electronic one-stop page for all relevant government bodies with a mandate on SPS measures.

The benefits of the SPS website include enabling users to:

- * know the SPS rules in Nigeria;
 - * know the SPS rules of their trade partner's country;
 - * have access to all the bodies relevant to their product;
 - * have health alerts on unsafe products. The website also enables the country to:
 - * give notifications on proposed changes in SPS rules and regulations;
 - * lodge complaints of discriminatory treatment in trade transactions.
- ii. WHO International Food Safety Authorities Network (INFOSAN) Focal Point/
INFOSAN Emergency Contact Point

INFOSAN was developed by the WHO to promote and improve the exchange of information among food safety authorities at national and international levels. As an integral part of INFOSAN, the WHO has created the following structures:

- * INFOSAN FOCAL POINT
- * INFOSAN EMERGENCY CONTACT POINT

The WHO manages INFOSAN and the website is www.who.int/foodsafety.

It is a network for the dissemination of important information on global food safety. The INFOSAN Focal Point receives INFOSAN information notes and disseminates them to stakeholders and other interested parties. One INFOSAN Focal Point per country is desirable, but there could be several Focal Points if responsibilities for food safety are divided among several agencies. NAFDAC serves as the INFOSAN Focal Point (IFP) for Nigeria. Our Regulatory Affairs Division receives and disseminates important information about global

food safety to relevant bodies and all interested parties. It maintains a coordinated information flow between the WHO and all interested parties and may initiate or suggest topics for inclusion as INFOSAN information notes to the public.

The INFOSAN Emergency Contact Point (IECP) for Nigeria is situated in NAFDAC's Food and Drug Information Centre (FDIC). The IECP has the responsibility to notify food safety authorities on food-borne disease outbreaks or food contamination events of international significance. It is also responsible for responding to various alerts on food safety. The IECP identifies the relevant departments in the ministries of Health, Agriculture and Water Resources and other relevant agencies that provide information on the outbreak of food-borne diseases or food contamination incidences in Nigeria, that require notification.

The global outbreak of avian flu virus that subsequently spread to Nigeria and all the activities of the various agencies of government to contain the spread is a good example.

The sensitivity of the information exchanged on the IECP network makes communication on this network very confidential. The IECP is expected to be an active member of the WHO Global Outbreak Alert and Response Network (GOARN) and must always be available for incoming emergency alerts. National IECs serve as official Contact Points under the Codex Guidelines for the Exchange of Information in Food Control Emergency. Therefore, in case of any food emergency, the IECP should be able to report the information required on the emergency on behalf of the government. The WHO requires only one Contact Point per country and for Nigeria, it is NAFDAC.

iii. Member of the Nigerian delegation to Codex Committees and Codex Alimentarius Commission meetings

NAFDAC is part of the National Codex Committee which draws membership from relevant government ministries, departments and agencies such as the Federal Ministry of Health (FMOH), the Standards Organisation of Nigeria (SON), the Federal Ministry of Commerce and Industry, the Nigerian Customs Service (NCS), the Federal Department of Fisheries (FDF) and the Federal Department of Livestock (FDL) both of the Federal Ministry of Agriculture and Water Resources, the Nigerian Export Promotion Council (NEPC), the Association of Food, Beverage and Tobacco Employers (AFBTE), academia, research institutes, the Nigerian Institute of Food Science & Technology (NIFST), public analysts and individuals with knowledge of Codex work and the Consumer Protection Council (CPC).

NAFDAC represents the country as part of the Nigerian Delegation to Codex Committees and Codex Alimentarius Commission meetings.

The National Codex Committee has four technical sub-committees, namely:

1. General Purposes sub-committee
2. Plant and Plant Products sub-committee
3. Animal and Animal Products sub-committee
4. Special Subjects sub-committee

The sub-committees deliberate on Codex Circular Letters (CLs) sent by the Codex Alimentarius Commission (CAC) to member countries, calling for government comments on Draft Codex Standards. NAFDAC chairs the General Purposes Technical Committee (GPTC) of the National Codex Committee. The GPTC is responsible for providing the secretariat facilities and also articulating the recommendations made at its meetings into national positions to be sent to Codex Horizontal Committee meetings, or submitted by the national delegation to the meetings. When a national position is agreed upon, it is sent to Codex through the Codex Contact Point (CCP) situated in the Standards Organisation of Nigeria and presented by the Nigerian delegation to the relevant Codex meeting.

National Roles

At national level, NAFDAC chairs the National Food Risk Analysis Centre (NFRAC) and the General Purposes sub-committee of the National Codex Committee (NCC).

Food Fortification and Breast Milk Substitute Code in Nigeria

NAFDAC expended tremendous energy and resources in the area of food fortification and development of a breast milk substitute code, which is strictly enforced.

Food Fortification Programme

The Nigeria Food Fortification Programme involves fortification of the following food items:

- a) Salt with iodine (and possibly iron).
- b) Flour, sugar and vegetable oil with Vitamin A.

The Universal Salt Iodisation (USI) programme was made possible through commitment by the Nigerian government and the salt industry. Effective multi-sectorial partnership was also key.

The Nigerian Government made salt iodisation mandatory by law in 1993, requiring 50 ppm at ports and factories, 30 ppm at retail and 15 ppm at household levels. (Levels are required to be higher when the salt is packed in larger containers, as it then loses its iodine content faster than when packed in smaller containers). The Law enjoys full enforcement, through inspection and testing by the Regulatory Agencies, namely the SON that sets the standards and NAFDAC that enforces the standards.

We created awareness on Iodine Deficiency Disorder (IDD) through sustained social marketing, with NAFDAC spearheading generic multi-channel communication campaigns to promote USI through billboards, newspapers, TV, radio, public notices, posters and publications in English and the vernacular. In addition to social marketing, sensitisation of the public was achieved through NAFDAC-championed High Level Advocacy that was normally led by the wife of the President, Ministers of Health, Industry and Commerce and key traditional rulers. This was followed by the launch of a USI logo to identify all iodised salt.

Through advocacy and enforcement of sanctions, salt manufacturers formed an umbrella association for effective self-regulation. This has ensured manufacturing and distribution of adequately iodised salt. We also encouraged salt industries to have efficient in-house Quality Assurance (QA) and Quality Control (QC) systems, which must be duly certified by NAFDAC.

Public and private sector partners formed themselves into an IDD–USI Task Force with defined complementary roles and responsibilities. Together they built human and technical capacity, developed internal systems and opened the multi-sector reporting channels necessary to consistently and continuously implement and monitor USI. Under this partnership, NAFDAC is responsible for enforcing compliance through monitoring at factory, distributor, wholesale and retail levels, creation of awareness, development of strategies to address shortfalls in salt iodisation and sanctioning of defaulters.

In implementing the USI programme, UNICEF provided us with tremendous support by supplying test kits and training for our staff members. In 2005, after an intensive assessment by a team of WHO/UNICEF/MI/ICCIDD experts, Nigeria was rated 100 per cent USI compliant and this gave our salt manufacturers the right to use the USI logo on their products.

However, results of recent surveys carried out in early 2007 showed that non-iodised salt was still being consumed in Benue, Ebonyi, Nasarawa and Taraba States, mainly from salt

smuggled into or produced locally by cottage industries in these states, making them Nigeria's iodine deficiency endemic States. In order to deal with the situation, we carried out sensitisation workshops on the need to consume adequately iodised salt, in collaboration with UNICEF, between October 2007 and March 2008 in the affected states. Benue State Government took the lead by planning the construction of a small cottage industry to refine and iodise salt from local producers and sell back to them. We also appealed to the big salt manufacturers who have made significant positive contributions to the Nigerian USI programme, to buy-off non-iodised salt from the cottage industries in these states, iodise the salt and sell back to the cottage producers in small packs at wholesale prices.

We also banned salt produced in 25kg sacks and gave the salt industries till the end of 2007 to mandatorily pack salt in small retail sizes (1kg and less) to enhance retention of iodine. Due to our success in salt iodisation, Nigeria has been celebrated in many international fora as the first developing country to achieve Universal Salt Iodisation (USI). We have also been invited through UNICEF to many countries (for example China and Ukraine) to teach them how we succeeded. We sustained this achievement through extensive advocacy on television and radio networks

As at the time of concluding this book, in the area of Vitamin A fortification, we have recorded about 80 per cent compliance for flour, over 90 per cent for vegetable oil and 100 per cent for sugar among medium and large-scale producers.

Enforcement of the International Code on Marketing of Breast Milk Substitutes in Nigeria.

NAFDAC is the regulatory body charged with responsibility for enforcing compliance with the National Code on Marketing of Breast Milk Substitute (BMS) in Nigeria. The World Health Assembly (WHA) adopted the International Code on Marketing of BMS in May 1981. Nigeria developed her National Code on Marketing of BMS in 1986. Four years later, the enabling Decree (now Act) 41 of 1990, as amended by Act 22 of 1999, was enacted. Both the National Code and the Act were dormant until April 2001, when the new NAFDAC management came on board. The dormancy was due to a number of limiting factors confronting the Agency, which included the following:

- Lack of trained staff members on the provisions of the Code, method of implementation and monitoring of code violations.
- Non-existence of monitoring tools, indicators and basic statistical data.

- Dearth of knowledge about the Code among key implementers and stakeholders, such as Health workers, the media and infant food marketers in Nigeria.
- Non-existence of the National Technical Committee on the Code (an advisory body as recommended by the World Health Assembly).
- Both the national Code and the Act did not capture the minimum standard stipulated by the International Code. Some parts actually contradicted the core provisions of the Code.
- The BMS marketers were working in the opposite direction to enhance their business.

On identifying these problems, we tackled them headlong. Realising that the training of NAFDAC staff would be the beginning of a radical response to the effective implementation of the Code, we kicked off the enforcement of the Code with a training workshop for NAFDAC staff at Ota, in Ogun State in April 2002. The workshop, which was very successful, was sponsored by UNICEF. Mrs Ellen Sokol, a legal adviser to UNICEF, New York and the author of the Code Handbook, was brought in as the main facilitator for the workshop. Further training for relevant staff members on Code monitoring and implementation were subsequently carried out over the years. NAFDAC is now equipped to be able to detect violations and enforce the Code effectively.

Other major activities carried out by NAFDAC to ensure compliance with the provisions of the Code include the following;

- Two weeks' training of some NAFDAC Staff including the head of Legal unit at the International Code Development Centre (ICDC) in Malaysia in 2003.
- Establishment of a National Technical Committee on BMS code, with NAFDAC as the focal point.
- Training of the members of the National Technical Committee.
- Development of monitoring tools including questionnaires and checklists for assessing compliance/violations of the Code nationwide. The tools were developed to cover relevant areas such as health facilities, health professionals, pregnant women and mothers of infants, retail outlets, the media, daycare centres, crèches and BMS manufacturers and their employees, labels, billboards and magazines.

- Development of a training manual on the Code.
- A pilot survey on monitoring of Code compliance was carried out between January and February 2005, in four health zones in the country, to fine-tune the monitoring tools.
- Training of Infant Food Marketers.
- Training of Code Watchers at the grassroots in various Local Government Areas of the country, beginning with the FCT, Abuja on August 2, 2006. The Code Watchers report violations to NAFDAC.
- Drafting of a comprehensive legislation on the Code – NAFDAC's, Marketing of Infant and Young Children's Foods and Other Designated Products (Registration, Sales etc.) Regulations, 2005. This captures all aspects of the international Code and eliminates all contradictions. The regulation was gazetted, launched and distributed to stakeholders including Infant Food Manufacturers in 2006.
- Conducting sensitisation workshops for media practitioners across the country on their roles in promoting the Code. During the workshops in Lagos and Kaduna on May 14 and 16, 2007, David Clark of the legal department of UNICEF, a world-renowned authority on Code matters from New York, was the principal facilitator.
- Conducting training workshop for doctors (in Pediatrics and O&G Departments) and nurses across the country in Abuja from May 21–23, 2007.
- Spearheading the celebration of the Annual World Breastfeeding week, which is marked on August 2 of every year.

Furthermore, in our grassroots consumer enlightenment campaigns, we educate Nigerians, especially mothers, to shun any deceitful advert and reject free gifts of baby milk that encourage the use of Breast Milk Substitutes (BMS). We educate them on the need to breastfeed their babies for as long as they can, as it is healthier for them and for their babies. Working mothers were informed that breast milk when expressed and stored is stable and wholesome for up to eight hours, even without refrigeration.

CHAPTER 16

GAINS AND ACHIEVEMENTS

Transparency in our regulatory processes enhanced our communication with stakeholders, thereby making them comply with NAFDAC regulations and guidelines. This helped us win public trust and confidence. It also contributed to the international credibility of the Agency, resulting in NAFDAC being chosen by several international organisations as the executing agency for their projects in Nigeria, the latest of which is the Global Alliance for Improved Nutrition (GAIN) Fund Project for Vitamin A Fortification. Other government agencies and regulatory authorities both within and outside Nigeria emulate our management style. Our remarkable paradigm shift is a great inspiration to many. In an article by Don C. Adinuba, in the Daily Sun newspaper entitled, “NAFDAC as a Study in Management”, the author recommended NAFDAC’s transformation as a case study for students of management and leadership.⁵⁶

Between April 2001 and October 2008, regulatory authorities from many countries and international bodies from around the world came at various times on study tours to NAFDAC, to learn from our experiences and strategies in the fight against counterfeit medicines and other substandard health sensitive products. Some of these study tours included;

Government of Southern Sudan: The team from the Drug Regulatory Authority of Southern Sudan came on a working visit in 2006 to study our experiences and strategies in the fight against counterfeit medicines.

West African Regional Programme for Health (WARPH/PRSAO): The body organised a study tour of NAFDAC for all the Medicines Regulatory Authorities in West Africa, to learn from our experiences and strategies in the fight against counterfeit medicines. The overall objective of the tour was to increase the knowledge of the participants from the various West African countries on our institutional and organisational system in the regulation of drugs and other health sensitive products. The tour was a prelude to the harmonisation of regulatory processes within the sub-region.

National Drug Authority (NDA), Uganda: The authority was mandated by the Ministry of Health to set up a framework for the regulation of food in Uganda. They visited NAFDAC from August 3-4, 2007, to familiarise themselves with our food regulatory system.

East, Central and South African Programme (ECSA): This group works on providing adequate micronutrients to women and children through the food fortification programme. The team visited NAFDAC to study our food fortification strategies, and to share our experiences and strategies in achieving the Universal Salt Iodisation (USI) certification.

Volume Of Counterfeit Medicine In Circulation

According to a study carried out by WHO and the Department for International Development (DFID) in 2005/2006, counterfeit drugs in circulation in Nigeria dropped from an average of over 41 per cent in 2001 to 16.7 per cent in 2006. They also found that drugs unregistered by NAFDAC stood at 19 per cent in 2006 as against 68 per cent recorded in 2002.

Earlier studies carried out by NAFDAC on the level of unregistered drugs in Nigeria showed a steady decline from 67.95 per cent in 2002 to 43.22 per cent in 2003 to 18.61 per cent in 2004, which is not significantly different from the 19 per cent for unregistered drugs obtained by WHO in 2006 (Figure 26).

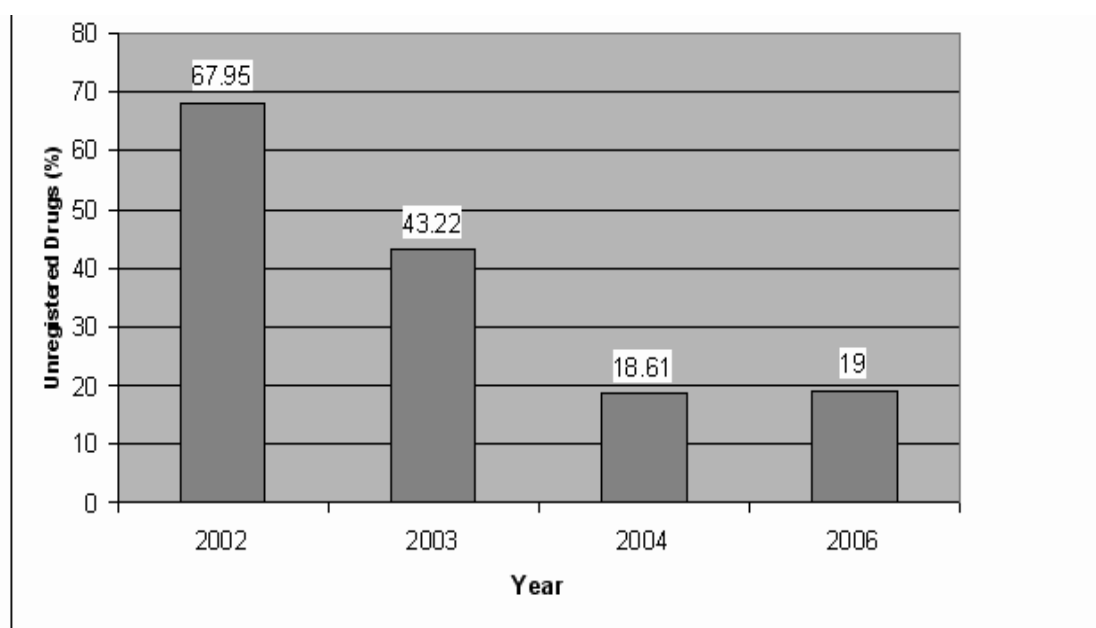


Figure 26: Percentage of Unregistered Drugs in Nigeria between 2002 and 2006 (Figures from WHO and NAFDAC Studies)

Reports From Hospitals on Declining Death Rates

There were encouraging reports of declining numbers of kidney failure patients and death rates in Nigeria. We wrote letters to most teaching and general hospitals in Nigeria requesting a compilation of all cases involving renal failure and deaths related to it on a monthly basis, so that we could establish a trend. The very few reports that we received were very encouraging. The verbal reports from doctors on their positive experiences from the use of medications were also very comforting.

Growth in the Health and Pharmaceutical Sub-Sector

At NAFDAC, we believe that the private sector is the engine for economic growth. Reforms in the pharmaceutical sector led to the unprecedented growth of our local pharmaceutical manufacturing companies. They consistently reported tremendous increases in their production capacities. The sector witnessed a 35 per cent increase in drug production in 2002. The Executive Secretary of PMG-MAN attributed the sector's improved performance to NAFDAC's 100 per cent pre-shipment inspection policy for all imported pharmaceutical products. This was in addition to the government policy which curtailed dumping of substandard products in Nigeria.⁵⁷ GlaxoSmithKline (GSK) recorded a 77 per cent growth in sales during the period. Jean Stephenne, GSK's General Manager for West Africa, attributed this huge jump to "NAFDAC living up to its responsibilities of enforcing strict compliance to product regulation".⁵⁸ May & Baker's profit rose by a whopping 88 per cent in the first half of 2003. The company was also optimistic of an even better performance in the second half of their financial year. Pharma Deko Plc. witnessed an increased demand for its products resulting in a 78.5 per cent increase in turnover in 2002.⁵⁹ The company declared bumper dividends in 2003.⁶⁰ Neimeth International Pharmaceuticals Plc. reported a 105 per cent increase in its profit before tax at the end of its financial year on March 31, 2003.⁶¹ The Nigerian Association of Chambers of Commerce, Industry, Mines and Agriculture (NACCIMA), in its review of the national economic performance for the 2003 fiscal year, stated that "the government target of achieving 65 per cent capacity utilisation in the economy was not realised. The only exception was the pharmaceutical manufacturing sector where the vigorous onslaught of NAFDAC on fake and substandard products pushed capacity utilisation to nearly 60 per cent".⁶² NAFDAC's activities, therefore, reinforced the confidence of investors in the pharmaceutical industry, as evidenced by the continuous upward movement in share prices of the pharmaceutical companies traded on the Nigerian Stock Exchange (NSE).

The NSE commended NAFDAC for the rise in healthcare stock prices, and cited the Agency's sustained fight against fake products as the reason for the greatly improved capacity utilisation of practitioners in that sector. The growth trend of quoted pharmaceutical companies from 2003–2005 showed between an 18 and 35 per cent increase in turnover and 12–25 per cent increase in profit. In its 2004 July monthly stock market review, the NSE showed capacity in the industry at 64 per cent, many points above the 54 per cent manufacturing sector average of recent times. Share prices of various pharmaceutical companies continued to increase steadily until 2008, when all quoted prices of companies in the stock market started experiencing a downward slide due to the global economic meltdown.

NAFDAC's impact stimulated demand, which in turn generated the need to rehabilitate, expand and modernise the factories of the manufacturers. They also opened new product lines to capture new markets. Many of the companies have returned to profitability and have become key players in the sector and indeed, in the Nigerian economy.

Several new pharmaceutical manufacturing companies have been established in the last few years and their number rose from 70 in 2001 to 150 in 2008. This has led to a tremendous increase in production capabilities of local pharmaceutical industries. In 2001, their production lines were producing less than 25 per cent of the country's drug need, against over 40 per cent production in 2007.

NAFDAC's reforms renewed confidence and increased patronage of pharmaceutical products produced in Nigeria by other West African countries and the international community. In 2002, the earlier ban placed on Made-in-Nigeria drugs by other West African countries was lifted. In fact, there is so much confidence in Made-in-Nigeria drugs that they are now marketed in many African countries. At the ports, we have intercepted drugs made in India but labelled "Made in Nigeria". In the United States of America, a Made-in-Nigeria medicine, Jobelyn, is officially accepted. All these underscore the growth and development being witnessed in the industry arising from NAFDAC's commendable works.

Many multinational drug companies are coming back to Nigeria because of the improved regulatory environment. Pharmacia divested but is now back as a fully-fledged market participant; Ciba–Geigy and Sandoz are now back jointly as Novartis. Others are Roche, Novo Nordisc, Sanofi Aventis and Astra Zeneca. Pfizer returned and made Nigeria their regional headquarters. Those that operate through third parties include Janseen Cilag, Servier

and Eli Lily. Reckitt Benckiser Limited, formerly importers of Dettol antiseptic disinfectant and soap, now produce locally.

“In the 2009 Business Monitor International updated Pharmaceutical Business Environment Rankings for Q408, which now covers Kenya and Algeria, Nigeria’s position has improved to a joint 12th place, up from the second last.”⁶³ “In a 5-year forecast, BMI estimates that Nigeria’s Pharmaceutical market will grow to US\$1.27bn in 2012, which is twice the 2007 figure of US\$596 million.”⁶⁴ These are clear indications of the improved regulatory environment brought about by our effective operations.

Increased Public Awareness

The public awareness generated by our regulatory activities resulted in the participation of the regulated industries, consumers and other stakeholders in the promotion of food and drug safety in Nigeria. This has awakened international consciousness that Nigeria is no longer a dumping ground for counterfeit medicines and other substandard regulated products. The increased consciousness brought about a high level of compliance with NAFDAC regulations.

Our reform activities have earned us much visibility and credibility over the years, to the extent that NAFDAC has become one of the most sought-after employers of labour in Nigeria today and our employees are viewed with utmost respect in society. This has unfortunately led to a situation where prospective applicants have fallen prey to unscrupulous agents, who promise them employment with NAFDAC.

Many opinion polls have rated NAFDAC as the best government agency in Nigeria. In one such poll conducted by The Guardian newspaper on the activities of NAFDAC, 83 per cent of the respondents rated NAFDAC’s performance as good or excellent.⁶⁵ In another public opinion poll conducted by the NOI, a Nigerian Based Opinion Research Organisation working in partnership with Gallop poll, USA, “NAFDAC was ranked as the most trusted and respected government agency in the country from among 17 government agencies in 2008. The result showed that 79 per cent of participants in the scientific poll voted for NAFDAC. The Agency has maintained this position in the NOI polls for the second year running and in the 2008 poll, the gap between NAFDAC and the agency that came second in both polls widened significantly.”⁶⁶ The outcome of these polls is real evidence of NAFDAC’s strong hold on the affection of the Nigerian public. Our staff members enjoy

high esteem, recognition and goodwill from the Nigerian public who appreciated the fact that our regulatory activities are succeeding in promoting good health for all.

Through our public enlightenment campaigns, consumers have formed the habit of scrutinising their drugs, food and other regulated products for genuineness by checking expiry dates and NAFDAC registration numbers before purchase or use. The uneducated also ask people to read the labels of products for them to ensure that they have NAFDAC numbers and that they have not expired before purchase or use. We successfully took our campaigns to the grassroots in most of the 36 states of the Federation and the Federal Capital Territory, to sustain this practice.

The general public was encouraged to report all known cases of fake products for investigation, publication and sanctions where applicable. Manufacturers and importers of unregistered products are compelled by our publications of unregistered products to submit their products for registration, to avoid the negative impact such adverse publicity would have on their products and organisations.

We have dedicated phone lines for public complaints and all enquiries are promptly responded to.

The international community has also attested to our good works. An excerpt of correspondence issued during the planning of a counterfeit drug conference for African countries in Dakar, Senegal and Cape Town, South Africa, reads in part:

“I am pleased to report that in planning for the conference, praise for NAFDAC and Dr. Akunyili has been universal. Everyone is very impressed with NAFDAC’s efforts and tenacity and for that reason, we would like to highlight NAFDAC during the conferences as a model for other countries in Africa, which are trying to win the battle against counterfeit drugs. Therefore, if it would be possible, we would be very appreciative if Dr. Akunyili could speak and participate in both Dakar and Cape Town version of the conferences.”

(Michael B. Adlin, Office of Enforcement, US Patent and Trademark Office, P.O. Box 1450, Alexandria, VA 22313–1450)

Destruction Exercises

From April 2001 to October 2008, we carried out 124 destruction exercises of counterfeit and substandard products valued at over ₦24.8 billion (US\$215.65 million). This represented

an 11,880 per cent increase in the value of products destroyed from 1994 to 1999 when the figure was about ₦204.12 million (US\$1.77 million).

There was a significant decline in the value of products destroyed in 2003 and 2004, compared to 2002 as shown in Figure 27. This showed a gradual decrease in the number of fake regulated products in circulation. By the year 2005, the fake drug barons had devised new methods to beat NAFDAC's ubiquitous presence in the traditional drug importation routes. These methods included importing counterfeit medicines via passenger aircraft with the products cleverly concealed in other consignments such as baby clothing. We therefore intensified surveillance and again caught them in their schemes as shown by the increased destruction for that year. Furthermore, the closure of the formerly impregnable Onitsha drug market in 2007 and the large volumes of counterfeit medicines carted away from the market and subsequently destroyed accounted for the spike in the value of destroyed drugs witnessed in 2007.

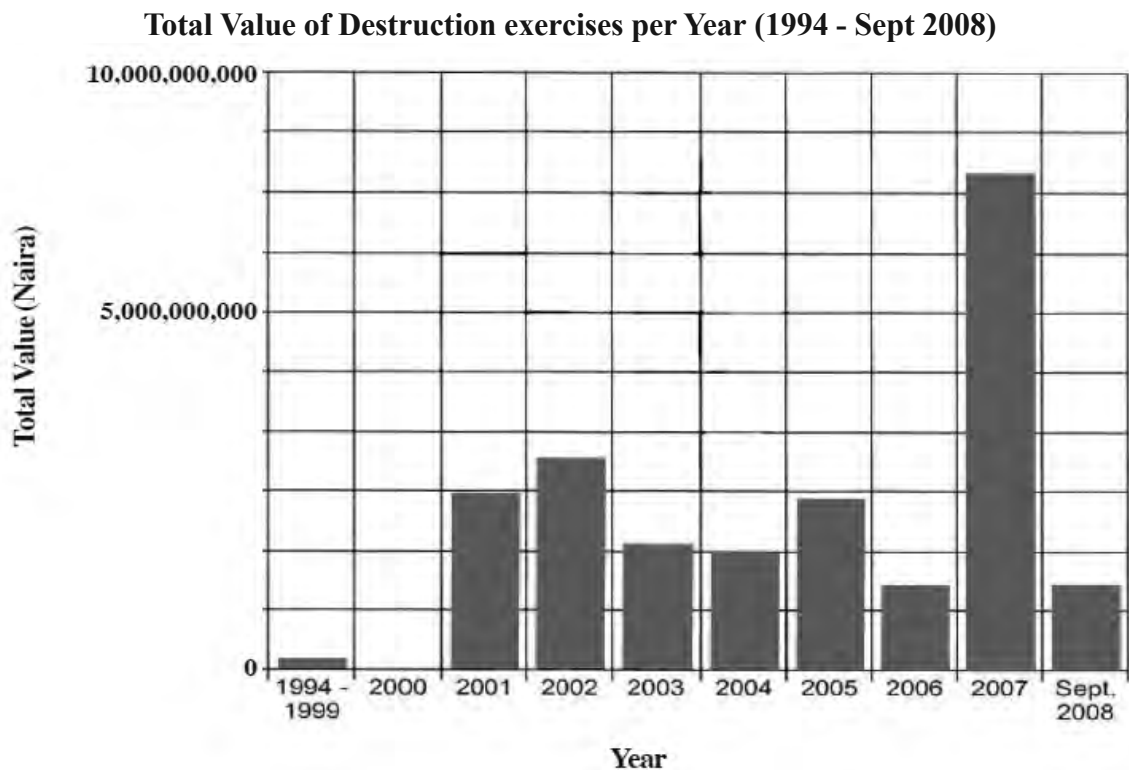


Figure 27: Values of Destruction Exercises

***Note:** 2000 was the year in which NAFDAC was under interim management and there are no data available*

Convictions of Counterfeiters

From April 2001 to October 2008, we secured 49 convictions in counterfeit and fake drug cases compared with 34 secured between 1994 and 1999. It should be noted that between 1994 and 1999 the Miscellaneous Offences Tribunal, which gave expedited action on cases, was in place. Once we secured a conviction, the courts always ordered the forfeiture and destruction of the offending products. Most of the convicted criminals paid fines. Only three people are currently in jail in Kano.

Establishment of National Pharmacovigilance Center

Our successful establishment of a National Pharmacovigilance Centre (NPC) in 2004 made us the 74th member country to participate in the WHO Drug Safety Monitoring Programme. By October 2008, the NPC had received 730 reports of adverse drug reactions. These reports enabled us to restrict or ban the use of some drugs such as the Dipyrone brands.

Prescription Requirements for Ethical Drugs

It is now a requirement for all injectables and sedatives to be obtained strictly on prescription from pharmacies and chemists in Nigeria. The next to be enforced is antibiotics.

Accreditation of Laboratory Facilities

All of our laboratory facilities obtained international accreditation as a result of the support by the International Atomic Energy Agency (IAEA) and our continuous upgrade of the laboratory facilities. Our Pesticide Residue Laboratory was upgraded to test for pesticide residues used in agricultural processes for raw materials intended for the food industry. On February 8, 2005, we commissioned an ultra modern Mycotoxin Laboratory, to ensure that food products meet all sanitary and phytosanitary conditions. This has improved Nigeria's reputation as a reliable supplier of good quality food products to the global market. The Pesticide Residue, Pesticide Formulation and Mycotoxin Laboratories are affiliated with the IAEA, while the Vitamin Analysis Laboratory is affiliated with the United Nations Children's Fund (UNICEF). Our Seafood Laboratory in Oshodi Lagos has European Union (EU) accreditation for fish and shrimp export and the World Health Organization (WHO) recognises the Central Vaccine Control Laboratory as the best in the West African sub-region. Both the WHO and the EU accredited our Yaba laboratory in Lagos.

Figure 28 shows the tremendous leap in the total number of samples analysed in our internationally accredited laboratories from April 2001 to September 2008 compared to analysis carried out between 1994 and 2000.

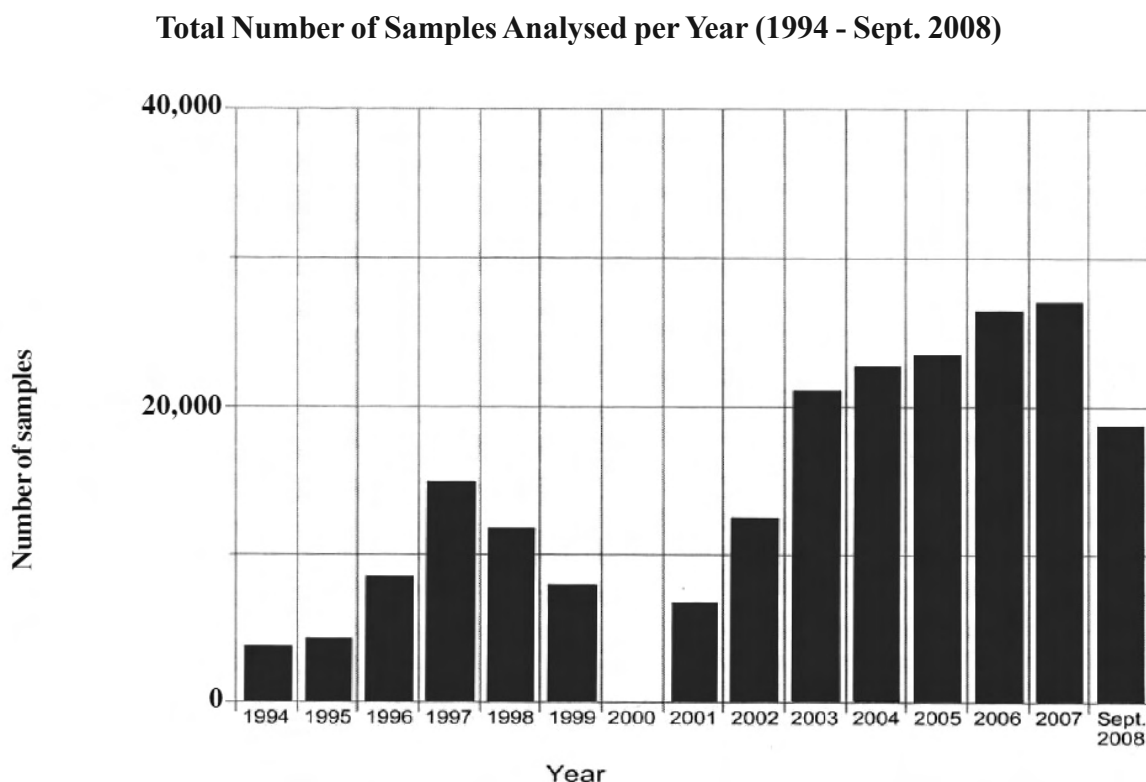
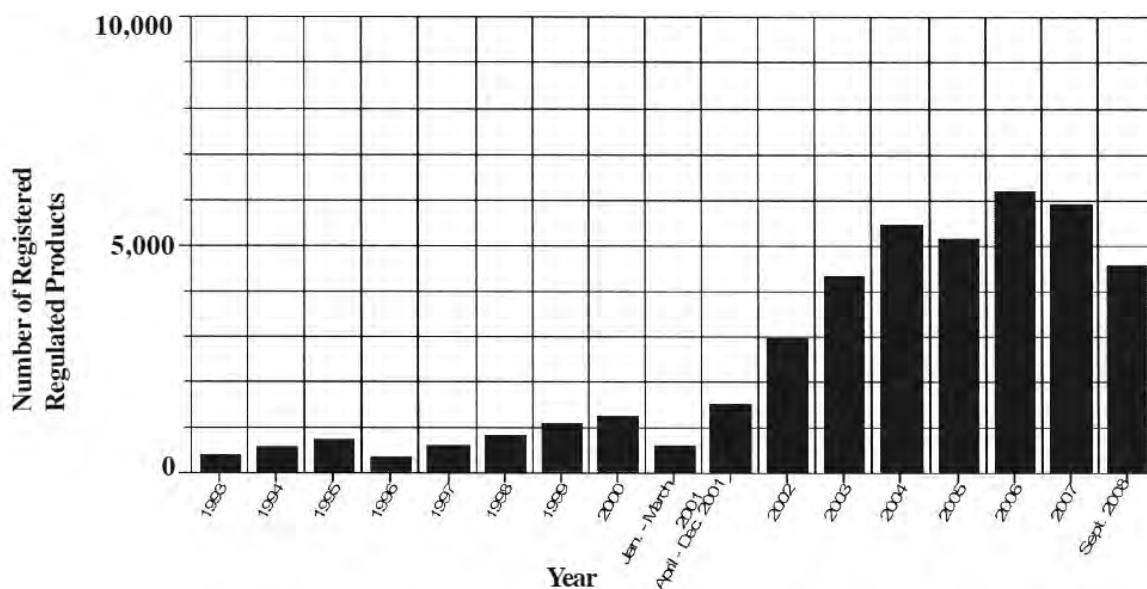
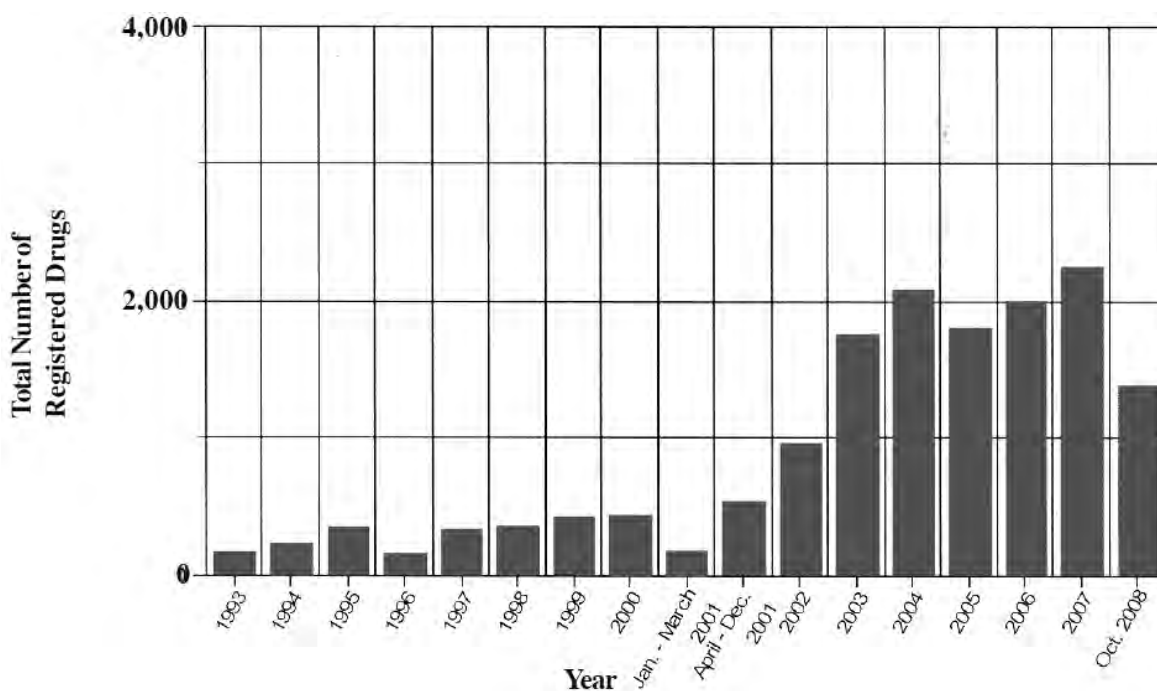


Figure 28: Total Number of Samples Analysed per Year from 1994 to September 2008

Drugs And Other Regulated Products' Registration

Under the Registration and Regulatory Affairs Directorate, 36,223 regulated products were registered from April 2001 to September 2008 compared to 6,471 registered from 1993 to March 2001. This represented a 559.77 per cent increase in product registration since the inception of the new administration as shown in Figure 29. Figure 30 shows the total number of registered drug products from 1993 to September 2008. This figure shows a clear-cut increase in drug registration from April 2001 to September 2008. This implies that drug manufacturers and importers appreciate the conducive regulatory environment and have started coming forward to register genuine products instead of smuggling unregistered and counterfeit medicines into Nigeria.

Total Number of Registered Regulated Products per Year (1993 - Sept 2008)**Figure 29:** Total Number of Registered Regulated Products per Year from 1993 to September 2008**Total Number of Registered Drugs per Year (1993 - Oct. 2008)****Figure 30:** Total Number of Registered Drugs from 1993 to October 2008

Inspectorate Activities

The activities of the Establishment Inspection Directorate (EID) increased significantly from April 2001 (Figure 31). The graph clearly shows the drastic rate of growth in inspection activities in the last seven and a half years compared to the previous years.

Total Number of Pre-Registration / Production Inspections between 1994 and August 2008

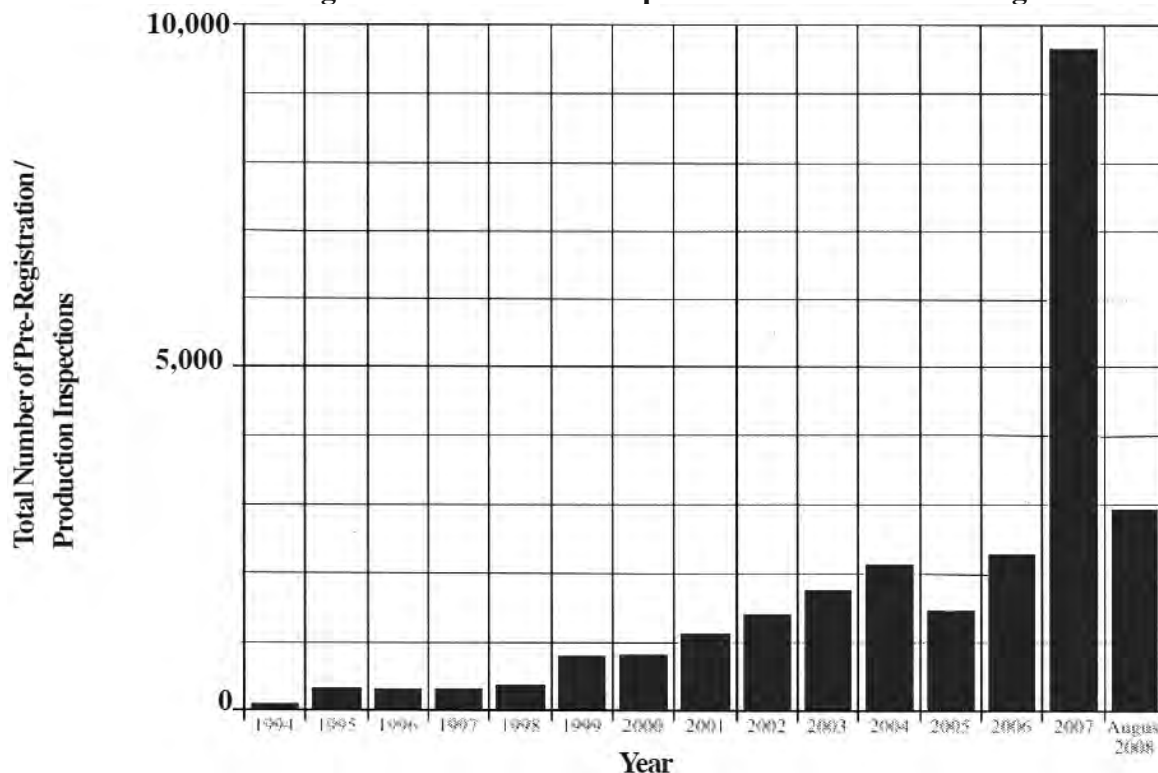


Figure 31: Total Number of Pre-Registration / Production Inspections between 1994 and August 2008

Staff Training

The Planning, Research and Statistics (PRS) Directorate conducted stimulating induction workshops for 259 and 138 new recruits in 2002 and 2003 respectively. 348 members of staff participated in our Good Manufacturing Practice (GMP) training in 2002. Another 109 were trained for effective implementation of the new tariff regime in the same year. In addition, Hazard Analysis and Critical Control Point (HACCP) workshops were organised in the six geopolitical zones and the three special zones, for both staff and stakeholders in the food industry. A total of 1,776 stakeholders and 420 members of staff participated. In 2004, we organised a finance workshop for 88 members of staff and a registration procedure

workshop with 174 participants in attendance; 412 regulatory officers were also trained on registration procedures in 2004. The PRS Directorate sponsored a national awareness-raising programme on contaminants and residues for food and drug production and processing. 1,333 participants from the regulated sector and 398 NAFDAC regulatory officers were trained during the programme.

Our establishment of a National Pharmacovigilance Centre highlighted the need for our employees to be trained on current regulatory issues and risk assessment of regulated products, particularly those for export. 140 staff members were therefore trained at a workshop organised for current regulatory issues.

NAFDAC staff have undergone numerous training courses locally and internationally on various regulatory functions. About 349 members of staff attended various international training programmes between 2002 and October 2008. Most NAFDAC members of staff are computer literate because it has been a condition for promotion since 2001.

Provision And Improvement Of Infrastructure

The creation of functional NAFDAC offices in all 36 states of the Federation and Abuja – the Federal Capital Territory, zonal offices in the six geopolitical zones, and three special zonal offices in Aba, Kano and Onitsha brought us closer to the regulated industries and the consumers. In addition, three narcotics offices were established in Abeokuta, Lagos and Port Harcourt.

The acquisition of a new Corporate Headquarters in Abuja was a monumental achievement for us, particularly as all the funds we utilised for the purchase were internally generated. Though NAFDAC, being a tax-supported government agency, ought to be fully funded by the Federal Government, we generate sufficient revenues to finance our capital/overhead budget, excluding personnel costs. Capital projects financed with our internally generated revenue include two gigantic warehouses in Oshodi, Lagos for the storage of pharmaceutical products undergoing investigations or laboratory analysis.

The old laboratories at Oshodi and Yaba (Lagos), Maiduguri and the new ones at Port Harcourt and Kaduna (staff quarters were converted into makeshift laboratories in Kaduna) were constantly upgraded. As I conclude this book, three new laboratories are nearing completion at Agulu (Anambra State), Calabar Export Promotion Zone (Cross River State) and Kaduna (Kaduna State). The drug laboratory in Yaba is fully automated with locally developed software and we intend to replicate this in our other laboratories. All our

functioning laboratories are equipped with state-of-the-art equipment, with chemicals and consumables directly supplied by Merck.

We also constructed land border offices and staff housing to provide the work environment needed for efficient monitoring of our land borders to check the importation of fake regulated products.

NAFDAC website services are available in all NAFDAC offices. The NAFDAC Regulated Products Automated Database (NARPAD) provides instant access to details of all NAFDAC registered products.

Excerpts of a letter to me from the Country Officer and Programme Manager of the IAEA TC projects in Nigeria to me as shown below, confirms the new NAFDAC's improved infrastructural status.

“... In my capacity as the Country Officer and Programme Manager of Nigeria IAEA's TC projects, I usually visit Member states under my responsibility within country programme Missions. To this effect, I undertook several missions to Nigeria. In this connection, I had the opportunity to visit the National Agency for Food and Drug Administration and Control (NAFDAC), including the Oshodi Laboratory and the Headquarters in early 2002. However, despite considerable improvements in pesticide residues capacity and the technical capability for monitoring pesticide residues in food and the environment, my different visits revealed some difficulties faced by the laboratories in the implementation of its duties. In this connection, relevant recommendations were made to the NAFDAC Senior management, with special emphasis to the establishment of a safety culture in laboratories, including establishing appropriate procedures for the routine laboratory control and validated multi-residue methods, as well as QC/QA procedures. In addition, it was recommended to take relevant action aiming to improve the working infrastructure, which suffered from several years of lack of maintenance as well as the Lagos weapons explosion (January 2002) in view of the fact that NAFDAC was not reflecting the kind of safety institution it might represent.

Fortunately, my latest visit this year (July 2003) gave me the possibility to be positively shocked after visiting NAFDAC infrastructure. I was really impressed by changes covering all aspects: infrastructure, equipment, embellishment of the workplace and most of all by the professionalism, motivation and team spirit shown by the personnel. The improvement made so far by NAFDAC in (i) establishing the mycotoxin laboratory and refurbishing

several other laboratories, (ii) establishing a safety and security culture in NAFDAC including appropriate QA/QC procedures for the routine laboratory control and validated multi-residue methods and (iii) responsible young and ambitious personnel carrying out work in the most professional way, were greatly appreciated by the International Atomic Energy Agency. I was really happy to note the complete positive change that this place underwent in just one year, the improvement of the institutional capabilities on quality control aiming to bring the country into compliance with international standards.

Vincent Nkong-Njock

Country and Programme Management Officer Department of Technical Co-operation International Atomic Energy Agency. November 6, 2003

The Food Fortification Programme

Universal Salt Iodisation (USI): The USI programme is successful in Nigeria with 100 per cent compliance at manufacturing and distribution levels and 98 per cent at household level. UNICEF rated Nigeria as the first developing country to achieve universal salt iodisation. This was celebrated at the Global Micronutrient Forum in Istanbul, Turkey, on April 17, 2007 and also in Nigeria on May 11, 2007. We have been invited by UNICEF to share our experience and strategies with countries yet to be USI compliant like China, Ukraine, Senegal and others. A joint International Meeting for the Sustained Elimination of Iodine Deficiency Disorder was organised in Beijing from October 15–17, 2003 by the Network for the Sustained Elimination of Iodine Deficiency Disorder, the Ministry of Health of the People's Republic of China and UNICEF. At this meeting, Nigeria's success with the universal salt iodisation programme was showcased. Developing countries were greatly encouraged by our successful implementation of the USI programme.

Our success with USI has significantly increased the credibility of the Vitamin A fortification programme in Nigeria. As at the time of concluding this book, we have recorded about 80 per cent compliance for flour, over 90 per cent for vegetable oil and 100 per cent for sugar amongst medium and large-scale producers.

Enforcement of the International Code on Marketing of Breast Milk Substitutes

NAFDAC now enforces the provisions of the International Code/National Regulations on marketing of BMS in Nigeria, thereby enhancing the health, nutrition and survival of the Nigerian child. The code has led to improvement in breast feeding which is a huge benefit to Nigeria. The most striking evidence is that anti-diarrhoea syrup has almost completely disappeared from Nigeria's pharmacy shelves.

On November 18, 2008, we commissioned a crèche of ten beds to cater for babies of ages 0 to two years born to our staff members, which is in compliance with the provisions of the National Breastfeeding Policy in Nigeria. The NAFDAC Abuja crèche is the first among government parastatals in the country.

NAFDAC Annual Essay Competition and NAFDAC Consumer Safety Club (NCSC)

The Agency's Catch Them Young project, which began in 2003 has yielded remarkable results. The number of schools participating in the NAFDAC Consumer Safety Club programme has gone up from 360 to 540 schools spread across the 36 states of the Federation and Abuja. The NCSC's website ncsc-nafdac.net is up and running to reach out to the increasing number of educational institutions that are interested in becoming members.

OTHER SUCCESS INDICES

Existing food and cosmetics industries are expanding their production capacities while new ones are springing up.

Sanitisation of table water has greatly reduced cholera and the outbreak of other water-borne diseases, which used to be rampant in Nigeria.

By 2001, over 95 per cent of Nigerian bakeries were using Potassium bromate as a bread enhancer, even though it was banned in the early 1990s in the rest of the world for its adverse health effects. A survey we carried out from May to November 2005 on all bread, found that less than 1 per cent contained Potassium bromate. A recent survey in 2007 revealed that the use of Potassium bromate by Nigerian bakers has dropped to less than 0.0001 per cent.

These achievements have become great morale boosters for the NAFDAC team. They have earned us the respect and support of consumers and the regulated industries, as well as the trust, support and political will of the Government. They also, to a large extent, helped to promote and sustain the change process. I have also enjoyed some personal moments of

celebration by virtue of my office, in the form of letters of commendation, as well as national and international recognitions and awards, which presently stand at over 500. The Agency also received several national and international awards, notable among which are: the first recipient of the Best Consumer Sensitive Government Agency Award, from the Consumer Advocacy Forum of Nigeria (CAFON) received on March 30, 2004 and the Global Anti-Counterfeiting Group (GACG) Award presented to the Agency on June 26, 2007 in Paris, at a ceremony to mark the 2007 World Anti-counterfeiting Day. Mr Val Usifo, the Chairman of the Port Industry Anti-Corruption Standing Committee, said that, of the numerous regulatory and law-enforcement agencies operating at the various national ports of entry, only NAFDAC could be exonerated from the corruption, extortion and illegal collection of fees from importers. He ascribed this to my transparent leadership of the Agency. This was reported in the Nigerian Vanguard newspaper of February 14, 2008.

CHAPTER 17

SUPPORT, APPRECIATIONS AND RECOGNITIONS FROM THE NIGERIAN GOVERNMENT, NIGERIANS AND THE INTERNATIONAL COMMUNITY

Support (Local and International)

The support we received from the Nigerian Government was immense. Favourable policies that enabled us to launch a successful fight against counterfeit medicines and substandard regulated products were established. The tremendous successes we recorded in the war are attributable in part to the remarkable support from all the Governors of the immediate past and present administrations, who ensured that we were able to implement our policies in their states without any hindrance. They facilitated our tasks by their supportive actions which, in some cases, included banning misleading advertisements of traditional medicines in all the print and electronic media in their states, allocating lands for the proposed Zonal Drug Distribution Centres (ZDDC), construction of new laboratories, and providing office accommodation for us in their various states. Even the wives of prominent government officials were not left out. As a show of solidarity and support for NAFDAC, they always made themselves available and associated with us by attending our enlightenment workshops for stakeholders. They also made other contributions.

Every government organisation wanted to align with the vision of NAFDAC to rid our country of counterfeit medicines, in one way or another. Some of these government organisations include the Federal and State Ministries of Health, Nigeria Police Force, Nigerian Customs Service, Nigerian Television Authority (NTA), Federal Radio Corporation of Nigeria (FRCN), Independent Corrupt Practices Commission (ICPC), National Intelligence Agency (NIA), Nigeria Immigration Services, National Drug Law Enforcement Agency (NDLEA), Nigerian Ports Authority (NPA), Nigerian National Shipping Lines (NNSL), National Programme on Immunisation (NPI), National Institute for Pharmaceutical Research and Development (NIPRD), National Health Insurance Scheme (NHIS), National Agency for the Control of AIDS (NACA), Standards Organisation of Nigeria (SON) and the Nigerian Judiciary.

We also received lots of encouragement from the good people of Nigeria. Nigerians from all walks of life extended unprecedented goodwill to us. Nigerians were very supportive and

their prayers, expressions of love and encouragement to us, through telephone calls, letters and poems, were very heartwarming and encouraging. As someone once said to me, “It is God’s bribe to you, madam.” It is indeed! Also, a commentator in a national newspaper once wrote, “The NAFDAC Director General is a revolutionary. She has not only changed NAFDAC, she has also changed the pharmaceutical industry in the country.”

Foreigners were not left out: notable among them is the British High Commissioner to Nigeria, Richard Gozney, who described me as an “angel of change”.

Nigerian banks also supported us by ensuring that Letters of Credit are only processed for drug importers after due clearance from NAFDAC.

The support we received from the Nigerian press in the war against counterfeit drugs and unwholesome food was overwhelming. They gave adequate coverage to all NAFDAC’s activities and promptly disseminated relevant information to the public. They were indeed our “town crier”. It is common to hear people say that no organisation has ever been so supported by the press as NAFDAC. I believe that this is because the Nigerian press was able to key into our vision.

Many world organisations and governments were magnanimous in their support for us. These organisations include: UNICEF, the WHO, PATHS, DFID, USAID, ENHANSE, the IAEA, the EU, the Environmental and Occupational Health Services Institute (EOHSI), Quality Control Services of India (QCS), the Government of India, Indian Professional Forum, Heads of other regulatory authorities, including India’s FDA, China’s FDA, the South African Medicine and Medical Devices Regulatory Authority (SAMMDRA), the USFDA, Indonesia’s FDA and Singapore’s FDA.

The Coca-Cola Company donated a Gas Chromatograph and a High Performance Liquid Chromatograph (HPLC) with Auto Analyzer; UNICEF provided 640 field iodide test kits; GlaxoSmithKline donated an HPLC; IAEA donated various equipment, including an HPLC; and there are many others too numerous to list here. UNICEF also assisted with workshops on breast milk substitutes; analysis of micronutrients in fortified foods; and field survey on salt iodisation levels at distribution and retail levels. The donation by Unicredit Group is worthy of special mention. Unicredit Group invited me to present a paper at the Central Eastern Europe Convention in Italy in September 2007. After the convention, the Group asked me what I wanted them to do for me. I requested that they buy vehicles for NAFDAC to assist in our regulatory activities. They accepted and paid about thirty-five

thousand euros (Euro 35,000) into NAFDAC account. The money was used in purchasing an operational vehicle for the agency"

Many national and international organisations offered training for our staff at no cost to NAFDAC. Every month within my first three years in office, we had at least 15 of our staff members undergoing various trainings abroad. A few examples of such training programmes were the IAEA sponsored training for Mycotoxin analysis of food and feed; pesticide residue analysis; monitoring of Mycotoxin contaminants and residues in food products etc; Montizen Nigeria Limited supported our optimal enzyme performance workshop in baking flour; and the College of Medicine, University of Lagos, sponsored a NAFDAC workshop on Quality Assurance. The WHO sponsored Diphtheria (DPT) vaccine production and its Quality Control for National Control Authority and Vaccine Technology.

Some other organisations that have sponsored various NAFDAC programmes include: Katchey Company Limited, Canvest, Dana Drugs Limited, Deevick Europe Limited, Pfizer Pharmaceuticals Limited, Evans Medical, Kneipe Nigeria Limited, Orange Drugs Nigeria Limited, Reckitt Benckiser Limited, Siperco, Smooth Food, U-Mec., Vitabiotics Limited and Wonder Foods.

Considering the fact that India is responsible for large volumes of counterfeit medicines in Nigeria, it is worthy of mention that the Indian Government through their High Commissioners in Nigeria, Shri Atish Sinha and Mr H.S. Viswanathan, played a very positive role in the efforts to eradicate the incidents of drug counterfeiting in Nigeria. Mr Atish Sinha showed a lot of commitment and attended a public hearing organised by the Nigerian National Assembly in 2001. He also attended the meeting we held with the health committee of the Nigerian National Assembly later in the same year. When Mr H.S. Viswanathan arrived in Nigeria for his assignment, I was the first public officer he visited. Both High Commissioners visited me a number of times to discuss the issue of drug counterfeiting with a view to helping to address the problem. They also organised training for NAFDAC staff in India.

The new High Commissioner, Mr. Mahesh Sachdev, also provided support for NAFDAC in the area of capacity building. The cooperation that we enjoyed from the Indian Government underscores the fact that the criminals are not enjoying the support of their government. In 2001, when Mr Gudal was in charge of the Indian FDA of Mumbai, he assisted us by sending a list of companies whose drugs failed quality tests in Mumbai.

Appreciations and Recognitions (National and International)

On October 1, 2002, Nigeria's President, Chief Olusegun Obasanjo, named me as one of Nigeria's Icons of Hope. On December 13 of the same year, I was conferred with the Order of the Federal Republic of Nigeria (OFR), by the President. During a dinner held at the Sheraton Hotels and Towers, in Abuja, to celebrate Nigeria's 43rd independence anniversary on October 1, 2003, the President had this to say:

“...When we came into government, one of the things that worried me tremendously was the issue of counterfeit medicines. I know not one, not two people who should not have died, but have died because of counterfeit medicines. Some people told me you couldn't do anything about it. They just gave up in despair. In desperation, they felt it was a hopeless situation. But will we say it is a hopeless situation today? NO! And why is it not a hopeless situation today? Because of one single individual who decided to do what is right even when men believed that it could not happen. Just a woman, a woman took the bull by the horn and she is making it happen. To happen in your presence and in my presence, in your face and in my face. Mrs Akunyili, I congratulate you and commend you. And this lady told me that if she continues to get the support she is getting, a few years from now, there will be no counterfeit medicines in Nigeria. So, it is happening and it can happen...”

On December 8, 2003, the College of Medicine of the University of Nigeria, Nsukka, my alma mater, endowed a Chair on Drug Quality Control and Management in my name. The Nigerian first lady graced the occasion.

Nigerian women also gave me their full support. The National Centre for Women Development (NCWD) recognised my outstanding contribution to the health of the nation. They named their biggest hostel after me and inducted me into their Hall of Fame on March 6, 2004.

I was humbled when I was nominated to carry the Olympic Torch in Cairo, Egypt, in 2004, for the Athens 2004 Olympic Games. I was unaware of the Olympic Torch Relay programme until Easter Monday, 2004, when my husband woke me up to tell me that I had just been chosen, along with four other Nigerians to carry the Olympic torch for Nigeria. The Olympic Torch Relay is a unique pre-Olympic event that kicks off the games and represents the Olympics' ideal of noble competition, global friendship and peaceful co-existence. Participation in the Olympic Torch Relay is regarded as a once-in-a-life time opportunity. In 2004 the Olympic torch passed through Africa for the first time, as part of its global journey.

And for the first time, Nigeria participated in the torch relay. Coca-Cola Nigeria Limited, the longest serving sponsor of the Olympic Games, supported the lighting of the Olympic Torch in Nigeria as part of their corporate social responsibility.

In selecting the Olympic torch bearers, Coca-Cola conducted an opinion poll, asking the Nigerian public the question: “Who inspires you?” The qualities to be considered in answering the question were:

- Someone whose life has enriched others.
- Someone who takes joy in life and possesses positive attitudes, which lifts the spirit of others around him/her.
- Someone who is extraordinary and proves that one individual can make a difference.
- Someone who embraces culture and history and passes the lessons unto the next generation, to ensure a brighter future.
- Someone who actively seeks to experience life’s adventures and challenges, big and small.
- Someone who typifies the Olympics’ team spirit and values.

It was reported that I had the highest number of nominations, apparently because of the work we were doing at NAFDAC. And off to Cairo I went with four others (Idris Abdul Karim, Pat Utomi, Tope Olowo and Segun Odegbami).

The Olympic Torch Relay was a big emotional moment for me. The knowledge that my fellow Nigerians gave me this honour and opportunity made it even more touching. Cairo was a great experience. It was different from the other trips I had made to Egypt. I felt like an athlete representing Nigeria, even though it was not a competition. It was an experience I will never forget.

On May 11, 2005, Chief Gabriel Igbinedion, the Esama of Benin Kingdom, the proprietor of Igbinedion University, Okada, the first private University in Nigeria, named a 100-room hostel after me. On November 26, 2008, the Igbinedion University School of Pharmacy was named after me.

In 2005, Silverbird Communications Limited, a private television outfit in Nigeria, asked Nigerians to nominate, through text messages, who would be the Silverbird Man of the

Year for 2005. At the end of the exercise across the country, the difference in votes between the runner-up and myself was so great that Silverbird refused to announce the breakdown of the results. Consequently, in January 2006, in a very colourful ceremony, I was celebrated as the Silverbird Man of the Year 2005. I was so honoured that I did not object to being called a man on this occasion! Once again, this was a show of love and appreciation by Nigerians.

Religious bodies and churches offered special prayers for me. They also offered me awards, many of which I accepted. However, I was particularly moved by the special prayers offered for me by His Holiness Pope John Paul II in 2003, which were delivered by His Grace, Bishop Anthony Gbuji.

Traditional institutions and their leaders have written to offer me chieftaincy titles, which I humbly declined except the titles from Igwe Ofomata of Nanka, my home town and that from Dr Olusanya Adegboyega Dosunmu, the Oba of Owu, the home town of President Olusegun Obasanjo. I felt that once I started receiving chieftaincy titles, there would be no end to it and it would become a distraction.

We also received numerous goodwill messages and news articles in the media, praising our efforts, from various individuals and organisations at a weekly average of 60 during my first year in office. At my second and third anniversaries in office and after the OFR award, hundreds of congratulatory messages were published in various national dailies in the country. At a point, I had to put out advertisements in some newspapers pleading with people to stop placing congratulatory messages for me. Some people apparently felt so compelled to express themselves that they ignored my request. I would have been happier if the money paid for these advertisements were channelled into promoting NAFDAC billboard campaigns. For every celebrated event or award for me or for the Agency, the fire incidents and attacks on my life, a myriad of letters poured in from individuals and organisations, affirming their unwavering support for NAFDAC's management.

On the occasion of my 50th birthday on July 14, 2004, there was an outpouring of love, support and appreciation from Nigerians and the international community. Newspaper congratulatory adverts appeared in their hundreds. I had a Thanksgiving mass at the Church of Assumption Falomo, Ikoyi on July 24, 2004. A reception party was organised by my friends. What touched and amazed me most was the turnout of people. They came in their hundreds. The event attracted a galaxy of personalities : the late first lady, Mrs Stella Obasanjo;

two former Heads of State, Generals Yakubu Gowon and Abdulsalami Abubakar, the Speaker of the Nigerian House of Representatives, Hon. Bello Masari, the Governors of Ebonyi, Enugu, Imo and Lagos states, Senators, Ministers, captains of industry and other eminent Nigerians. The international community was well represented. I was moved to tears as Nigerians from all walks of life showered me with gifts and accolades. PMG-MAN presented me with a bulletproof BMW car as a token of appreciation for the reform in the food and drug sectors. This was also their way of contributing to my safety after the assassination attempt on my life some months earlier. The tributes published in the national dailies and letters written to me by individuals and associations were great energisers for the work ahead. Some of the tributes had titles such as: "Celebrating A Woman with Passion for Work", "Dora Akunyili – A PR Case Study", "National Leadership –The Akunyili Example", "She is Different", "A Top Brand Called Akunyili", "Lady of Integrity at 50", "Akunyili – A Dogged Fighter at 50", "Akunyili – Tribute to an Icon of Hope", "Dora Akunyili – A Passion for National Service".

The celebrations were not over yet because on August 28, 2004, my first daughter Ijeoma married her Ivorian husband Aristide Achy Brou in Abidjan, Ivory Coast. For this event, over 500 people travelled from Nigeria to Ivory Coast to support my family, all at their own expense. Their presence again showed earnest appreciation and genuine support.

On the international scene, on April 28, 2003, the European Market Research Centre (EMRC) conferred on me the EMRC EUROMARKET award in Brussels. The EMRC promotes economic and trade relations between business leaders around the world, especially between the EU and non-EU companies and countries. They do so by appreciating the activities of business leaders who have contributed substantially to the development of economic cooperation within their regions and towards the EU. I also won the award for 2005 and 2006.

It was a testament to the work of our organization that in 2003, at the 11th International Anti-Corruption Conference (IACC) in Seoul, South Korea, I was conferred with the 2003 Integrity Award, amongst the three final nominees, out of 600 pages of dossiers on nominees received from all over the world by Transparency International (TI). The presentation ceremony was attended by thousands of people from across the globe, including the President of South Korea. Indeed, receiving the award was a huge achievement not just for me, but also for Nigeria. Firstly, it came shortly after Nigeria was declared as the second most corrupt

country in the world, by the same awarding body, TI. This means that TI recognises that there are still honest Nigerians. Secondly, I was the first African and the first woman to win this coveted award which I dedicated to all those who shared our vision to eradicate counterfeit medicine from Nigeria and are actively working to accomplish this.

It is worthy of note that in 2007, Justice Emmanuel Ayoola, the Chairman of ICPC, one of the two Anti Corruption Agencies in Nigeria, invested on me the title of Grand Patron of the National Anti-Corruption Volunteer Corps. According to Justice Ayoola, the investiture was in recognition of my leadership qualities, integrity and commitment to the anti-corruption campaign in Nigeria. As I was about to conclude this book, the Nigerian High Commissioner in the UK, Dr. Dalhatu Tafida, received on my behalf, an Honorary Membership Certificate of the Royal Pharmaceutical Society of Great Britain.

A few prominent awards/recognitions which I received include; Total Quality Leadership Award (2003) by the African Institute for Democracy and Good Governance; Special Award for Combating Economic Crime (2004) by International Chamber of Commerce-Commercial Crime Services (ICC-CCS) - London; African Civic Responsibility Award (2004 - 2005) by African Times-USA; Quintessence Award (2004) by African Writers Endowment Inc. USA; SACAIDS Humanitarian Hero of our Time Award (2005) by Save African Congress for AIDS (SACAIDS), New York; FIP Pharmacist of the year Medal Award (2005) by International Pharmaceutical Federation (FIP) Industrial Pharmacy Section (IPS); Honoured as one of the 18 Heroes of Time Magazine Worldwide in Health (2005) by Time Magazine, New York; Grassroots Human Rights Campaigner Award (2005) by Human Rights Defense Organisation (International Service) in British House of Commons, London; Honorary Degree of Doctor of Laws by University of Bristol, UK (2006); Honorary Georgia Citizen by The State of Georgia, USA (2006); Integrity Award by Code of Conduct Bureau (2007), Nigeria; the 2008 African Heroine Award by Ohio State University African Students Union USA (2008) and the Flour Fortification Award (2008) by the Flour Fortification Initiative in Arusha, Tanzania.

These and other awards I have received are listed chronologically in Appendix 24, and some press cuttings are shown in Appendix 25.

Many Nigerians have also written heartfelt poems to me in appreciation of the work we are doing.

COMMENTS BY STAFF OF NAFDAC ON THEIR EXPERIENCE WORKING WITH ME

Mrs Doris Amlai, Director, Ports Inspection Directorate

“... Prof. Akunyili in my opinion can be described as:

- A dogged fighter who is very energetic and never gives up.
- Passionate about everything she believes in.
- Bold and courageous.
- Aiming at perfection and excellence in all endeavours.
- An advocate of quick service delivery, without compromising standards.”

Mrs A.O. Olamuyiwa, Director, Planning, Research and Statistics

“It was celebration within me the first day I met Prof. Dora Nkem Akunyili in April 2001, when she was formally introduced to us at the NAFDAC office in Oshodi, Lagos as our new Director General. That day, I saw shrewdly in her, a hard working and prudent personality that would be a disciplinarian. Over the years, she has rightly proved my first impression of her. She is a woman that is so interested in the work she is mandated to do, that has left no stone unturned to ensure that NAFDAC’s regulated products are safe for consumption.

Nationally, she has attained a popularity that no public servant has ever attained before in this country. She has also introduced Nigeria to the International community in a big way. She has shown the world that Nigeria is a country with an effective regulatory system for food, drugs and other regulated products.

Nigeria’s exposure to the International Community is not limited to her personal visits. She has provided opportunities for staff members to be exposed to what obtains abroad in the manufacture of regulated products. This is through foreign Good Manufacturing Practice inspections which she made mandatory for all cadres of staff. Experience gained by staff during these visits can never be over emphasized or forgotten.

She has also restructured NAFDAC to a befitting standard. She has performed extremely well even at the expense of her life. In this way, she has propelled staff members to imbibe this culture of hard work. Working with her has been a jolly good experience.

To crown it all, on March 30, 2004, NAFDAC became the first recipient of the Best Consumer

Sensitive Government Agency award, from the Consumer Advocacy Forum of Nigeria (CAFON).”

Mr Hashim Ubale Yusufu, Director, Technical Services Unit

“I joined NAFDAC in 1994 when it was just starting, as an Assistant Chief Regulatory Officer (ACRO). I was, however, seconded to the Government of Jigawa State in 1999, where I served as a member of the State Executive Council till August 2002. It was during this period that I met with Prof. Dora Akunyili as the new Director General – NAFDAC and she passionately appealed to me to return and work with her. I agreed and resumed work immediately. Ever since, I have worked closely with Prof. Akunyili as head of Technical Services. My assignments include representing her at various local and international meetings and conferences, reviewing technical documents and building effective international collaboration, such as WADRAN and IMPACT, towards fighting drugs counterfeiting. This experience has greatly enriched my knowledge and increased my skills and expertise in regulatory activities.

I find Prof. Akunyili’s leadership style quite unique, particularly her strive for perfection, which is indeed a rare attribute. Her selfless service and dedication to duty remains unparalleled in my entire civil service career. I believe Nigeria and the international community strongly need people like her to enhance the struggle towards attaining better health for our societies.”

Mr Nnamdi Ekweogwu, Director, Finance and Accounts

“When I joined the new management of NAFDAC under the leadership of Prof. Dora Akunyili in 2002, our main goal was to surmount the challenges confronting NAFDAC, assist the Director General in bringing about firm control on issues of finance and administration and effectively position the Agency to combat the menace of fake and adulterated food and drugs in Nigeria. We therefore, embarked on empowering members of staff in our zonal and state offices and strengthening our infrastructural facilities.

We introduced the imprest system to empower them financially, enable them take decisions and to literally make them to be seen as the Director General at the state and zonal levels. Various welfare packages were introduced to motivate staff. We also established a salary payment date of 28th of every month. Most of these packages had to be pushed through the Agency’s Governing Council, with its attendant difficulties. However, the doggedness, resolve, vision and strength of Prof. Akunyili helped push them through.

Her decisiveness in matters of staff welfare and discipline encouraged the entrenchment of hard work, respect for authority and transparency among members of staff. This in some cases was at the expense of personal and/or staff happiness.

Generally speaking, working with her is not a tea party – one is constantly on one's toes. However in all, the effectiveness and efficiency of the Agency came uppermost in the final decisions taken.”

Mrs H. Keri, Director, Establishment Inspection Directorate

“My experience and relationship with Prof. Dora Akunyili as the Director General of NAFDAC in the last 7½ years has been that of purposeful leadership, which gave me a free hand to exercise my potential as a pharmacist to the fullest.

It was a roller coaster ride of firstly, laughter, openness, approachability and yet one of firm, sometimes scary/frightful, stern corrections, advice and yes, even punishment (reminds me of my mum), all with a view to bring out the best in me as a professional in regulatory practice. However, by the 4th year, I wasn't allowed to make errors. This huge expectation further propelled me to pursue excellence in everything I do including personal tiny details such as dressing, eating habits, need to exercise, etc. She has also affected my personal life. She would remember my niece who lost her dad (the Galadima of Uba) in 2004, in terrible circumstances, hug her for comfort and send her out to shop. She would empty her bag for one of my sons studying abroad – oh the heart of a mother!! However, I can assure you that you don't want to be around when she gets mad!!

God has used the Professor we fondly call “Adda” in fulfulde meaning “elder sister”, to reward hard work. I bless the Lord for causing me to go through her tutoring, right from my days as head of Laboratory, which at once elated me and my then staff members. This new direction also made, nay compelled, us to go back to the drawing board and review laboratory systems for Drug Control in Nigeria. This experience is Unforgettable!”

Mrs A.C. Madukwe, Director, Registration and Regulatory Affairs Directorate

“Working with Prof. Dora Akunyili in the fight against counterfeit medicines is like waging real war with an Army General. Strategies are mapped out with a view to dismantling and destroying the numerous tactics of the fake drug barons (enemies of the consumers). She waged the war with so much passion that she put in place all that it takes for a mortal to win a war.

I found her, a benevolent and firm patriot who exhibited all the characteristics of a good leader throughout this period. The difference from what it used to be before she took up the responsibility as Director General of NAFDAC in 2001 was very clear, as can be seen by all the achievements of NAFDAC today.

Working with her was interesting and at the same time challenging.”

Mrs Y.O. Oni, Director, Administration and Human Resources

“I met Prof. Dora Akunyili for the first time in April 2001, shortly after she was appointed the new Director General of NAFDAC. That was during a ‘meet you, meet me’ meeting, she called to brief members of staff on her mission and the direction she hoped to chart for the Agency under her leadership. From that moment, I saw a leader with passion for the job and open to ideas. These thoughts were not wrong, as events were to prove later.

As time went on, a Lagos liaison officer was needed. An election was conducted to choose the candidate from the management staff. It was a kind of popularity test, solely determined by members of staff. I emerged second in the election in the midst of others who were Deputy Directors and she asked who I was. I was Chief Admin Officer (CAO) at the time.

Two weeks after this incident, she redeployed me to Abuja to work with her as the head of the Administration Department and this has impacted tremendously on me. Through her philosophy of work, she has lifted the Agency to be at par with other reputable international organisations. Her policy on foreign GMP inspections has given some members of staff who hitherto had no hopes of seeing the four walls of an international airport the opportunity to travel outside the country and expand their horizon. She has given members of staff renewed sense of confidence and fulfilment. Perhaps the Akunyili phenomenon will remain with the Agency for a long time to come.”

Mr Mobojuru, Deputy Director, Finance and Accounts

“I was employed into NAFDAC through competitive written and oral tests conducted in the year 2001. Prior to this time, I had experienced the happenings both in public and organised private sectors that only your connections and who introduced you to the employing authority will earn you employment in various establishments. I knew nobody, I contacted nobody and yet, I was the only person employed for the position of Deputy Director, Finance and Accounts, out of about 200 candidates that sat for the examination. What a transparent and rare occurrence. This of course told me the likely nature of the Chief Executive in the person of Professor Dora N. Akunyili OFR, that I would be working with.

Prof. D. N. Akunyili is a visionary leader, highly proactive and thorough. She has moved NAFDAC from an obscure entity to an internationally recognized one. Prof. Akunyili has achieved 'firsts' in several areas for the Agency and country by extension, especially in the area of her relentless efforts at drastically curtailing, if not completely eradicating the incidences of fake and adulterated products."

Mr Festus Okwudili Anumba, NAFDAC (EID), Makurdi Office, Benue State

"The problem of Counterfeit medicines is hydra-headed and like an Octopus, it has many tentacles and is deadly on all fronts. A country with the problem of counterfeit medicines can be likened to a country under siege, the enemy closing in on all fronts to squeeze life out of it. Politically, economically, socially and health wise, the Nigerian state was under serious threat and at the brink of collapse as at 2001, due to the scourge of counterfeit medicines, which statistically stood at about 85 per cent.

To rescue Nigeria from the scourge at the time needed something in the realm of the extraordinary. Like the seasoned commander (Field Marshal) with clear vision, Prof. Dora Akunyili emerged and doggedly beat back the enemy and the grip/squeeze loosened. Hence the scourge as at today is adjudged to be in the range of single digit. Thanks to Prof. Dora's amphibious approach. She engaged the scourge on all fronts with every arsenal at her disposal. This she did with obsession/passion, unmindful of the inherent dangers to her personal/family life. Yes the dangers really reared up their heads, but due to her commitment, she was and is still undaunted. She has invested her life for the health of the citizenry, such that this country shall no longer be under the siege of counterfeit medicines.

Courtesy of her altruistic leadership, Prof. Dora has become the beautiful bride of our nation, a distinguished citizen of the world and an envy of other nations. Drug Regulatory agencies of countries in Africa and beyond have been so sensitized and poised by the waves emanating from Prof. Dora's global war against counterfeit medicines (one woman riot squad), hence the emergence of WADRAN, IMPACT and others.

Working with Prof. Dora is very demanding and challenging. However, it is inspiring, fulfilling and encouraging. As an officer under her, you must produce the right result. Furthermore, it is exciting, considering the fact that the public is excited just by being introduced as a NAFDAC staff. I say with positive nostalgia that Prof. Dora Akunyili has set a precedence and standard which has never been and will be very difficult to beat for the 'size of the shoe' is really not in the open market."

Mr. Ejiofor, Deputy Director, Legal Unit

“The arrival of Professor Dora Akunyili into the anti counterfeiting equation in April 2001 as the Director-General of NAFDAC marked a watershed in the lives of the legal officers of NAFDAC. If there was any Legal Unit prior to April 2001, it was at best a name devoid of any existence or life. With the coming of Prof., a true and functional legal unit was birthed. The legal unit was thereafter infused with life and stoked up with the flames of nationalism and the ‘yes we can’ belief.

Professor Dora Akunyili empowered the legal unit by the creation of the enabling environment and the provision of essential law books. More importantly, legal officers of the Agency were given the opportunity, for the first time since the establishment of NAFDAC, to prosecute cases at the various courts across the Federal Republic of Nigeria. Her vision and belief in the legal officers paid off by the numerous civil cases won and the convictions secured in counterfeit drugs cases by the legal unit. It was quite epoch making.

My working relationship with Prof. in the saddle was warm, transparent, professional and honest. There were instances, I argued with her in the course of our work and she neither intimidated nor threatened me, but instead, accepted superior logic, opinion or argument at the end of the day. She was quick to overrule herself on issues in the face of any superior proposal or idea. Her humility at the place of policy formulation and intellectual discourse was quite disarming. In spite of the fact that I never knew Prof. before she assumed office in April 2001, she challenged and brought out the best in me. Her DNA is Dynamism, Nationalism and Altruism. It was great working with Professor Dora Akunyili.”

Mrs. Adeline Osakwe, Deputy Director, PVG/FDIC

“I joined NAFDAC from the Petroleum (Special) Trust Fund (PTF), in January 2002, as Deputy Director Special Duties, in our Lagos Office. In working with Prof. Akunyili, I developed the desire to conclude each assignment to her satisfaction and this meant at times overstretching the limits of my capacity. As someone in charge of special duties, it meant that any assignment that did not fall within a particular schedule comes to me. I enjoyed this as it made the task more interesting and relieves me of drudgery of routine. Each assignment becomes entirely a new experience for me. It was at this stage that I started experiencing the adage that ‘the reward for hard work is more work’. I appreciated this since it was an opportunity to be mentored. She gave out assignments with high expectations and if your performance is ‘exactly’ as she expects, you are celebrated and

more work will be given to you. If you miss a few things, you will be put through on how best to do it and left to get it right. One striking aspect of Prof. Akunyili's relationship with staff is that she always respects contrary opinion provided one proffers superior argument. She has encouraged me to aspire to any length through capacity strengthening in different areas. I can tell when she is happy with my work output and when she is not, simply, by the way she addresses me or looks at me. The difference is always clear. Getting her approval for a job well done gradually became a motivating factor for me, in addition to self fulfilment in doing the NAFDAC work.

When I lost my husband in 2004, she tried so much to encourage me to be strong for my family in so many ways and even paid my last child's school fees for upwards of one year. Her reason being that she would not want me to lower my son's standard of education at Corona Schools, because the father was no longer there. This really touched me and made me more determined to ensure that I give my best to the Agency.

In 2006, Prof. Akunyili told me that she wanted me to be transferred to Abuja from Lagos to head the Pharmacovigilance Center there. I gave her what I thought were cogent reasons why my job of coordinating many assignments is better done from Lagos rather than Abuja and that this movement would disorganise my family, which was then trying to stabilize. This conversation took place in South Korea where I accompanied her to attend an International Conference of Drug Regulatory Authorities (ICDRA) in April. At the end of the conversation, I actually thought the matter had ended. Little did I know that as soon as we came back, she had given instructions that I should be immediately transferred to Abuja. I picked up a few lessons from this. Firstly, that sentiments had no place in the scheme of things if one wants to succeed and secondly, individual objectives have to be subsumed in the organisational objectives/goal.

My experience with Prof. Dora Akunyili has taught me that one needs to continuously build/strengthen capacity to function effectively. Through her transparency, integrity and passion for work, she has positioned herself as a role model and mentor to me. With her, there is no room for a dull moment, but at the end of it all, one feels proud to be part of this success story."

Mrs. Elizabeth Awagu, Special Assistant to Director General

“‘The fight against Fake Drug is a war we must win.’ This is a constant statement Prof. Dora Akunyili drums into our ears. She has a passion for freeing Nigerians from the bondage of counterfeit medicines and other adulterated regulated products, which have killed millions of Nigerians. As a General, a good one indeed, she led us by example. She has zero tolerance for corruption and calls for hard work, honesty, transparency, integrity, equity and selflessness. In working with her, there were a lot of sleepless nights, sacrificing our social lives and the comfort of our families to be able to succeed. In addition, our belief in divine assistance and total support from God was strengthened after the assassination attempt on her life in December 2003. We were terribly shaken. She exhibited an exceptional courage and her commitment in winning the war was greatly strengthened. This was encouraging to us all. There were a lot of other challenges, but the astute leadership and simplicity of mind of our General, Prof. Dora, led us to the victory we have so far achieved in this war against counterfeit medicines and other substandard regulated products.

As her Special Assistant in Lagos for the past seven and half years, I was privileged to work very closely with her. I learnt and imbibed a lot from her leadership qualities and interpersonal relationship, which made her that victorious General. I give God the Glory.”

Mrs N. Mainasara, Deputy Director, Food Registration Division

“I have worked with NAFDAC since inception in 1993. Prior to 1993, I was a staff of the Food and Drug Administration and Control of the Federal Ministry of Health from 1980. During this period, the leadership and organisational structure, staff motivation and welfare was very poor. However, with the new management of Prof. Dora Akunyili, procedures were streamlined, delays in product registration was reduced. Staff were being trained and retrained and we had a Director General, who was accessible to all, staff and outsiders alike.

Working with Prof. Dora Akunyili has been challenging, fulfilling, inspiring, motivating, intellectually stimulating and I have personally imbibed her ‘can do’ attitude, workaholic nature and integrity in all areas of my life. Her leadership and management abilities have completely re-oriented me and the attitude of members of staff working with me. Anywhere I go, abroad or within Nigeria for workshops, seminars, training, etc., people say ‘please extend my appreciation to your Director General, Dora and her staff’. Nigerians say ‘we are praying for her’. Foreigners say ‘she is one in a million’. I tell you, meeting her is an experience you will never forget.”

Mr B.D.S. Fraden, NAFDAC, Brinin Kebbi, Kebbi State

“Prof. Akunyili’s unwavering/resolute determination to fight fake and counterfeit drugs is contagious. It has given staff members the confidence to face the menace squarely and to risk their lives for Nigeria. It has also made Nigerians very aware of what they should expect from regulated products and has challenged other regulators (both nationally and internationally) to rise to their responsibilities. The Merchants of fake and counterfeit drugs are no longer as daring as they used to be.”

Mrs O.M. Olarewaju, Unit Head, EID NAFDAC Rivers State

“There is no doubt that the War on Counterfeit medicines embarked upon pre- and post-2001 when this administration came on board cannot be compared. As a field officer, we have noticed an increased awareness in the public knowledge of counterfeit medicines. There has been increased public confidence on the ability of NAFDAC in tackling this problem. This is evident in the flow of consumer complaints and alerts that have been received and commendations on NAFDAC’s prompt response and actions. This public confidence engendered so far, is also a pointer that this administration has made its mark.”

Mr Dauda Dutse Gimba, Chief Regulatory Officer, North-East Zone

“The post 2001 era ushered in an unprecedented period of clarity of purpose, distinctive focus and unwavering commitment to the fight against counterfeit medicines. These, in my opinion, were achieved by the Director General Prof. Dora Akunyili OFR, through her belief and faith in God and Country. Without ambiguity, she developed her road map to curb the menace and has ever since, insisted and successfully ensured strict execution by management and staff of the NAFDAC Brigade. The closure of notorious markets like the Onitsha and Kano Drug markets was considered impossible even during military regimes. The arrest and prosecution of hitherto untouchable drug barons were considered suicidal and contemplated only by the insane. She came, she saw and she conquered them one after the other. The will of the Nigerian Government is now under trial, to determine if the battle is decisively concluded or allowed to fizzle out. May God bless Prof. Dora Akunyili OFR

Mr I.D. Nwosu, Deputy Director, North-West Zone, Kaduna

“The last seven and half years of working with NAFDAC has been very fulfilling and rewarding for me. During this period, the Agency recorded tremendous achievement by upholding the rule of law, due process, encouraging team work spirit, transparency and

accountability, with a firm commitment to professional ethics in regulatory activities.

These achievements were due to painstaking guidance of the Director General, Prof. Dora N. Akunyili.”

Mr. Momodu-Segiru Momodu, Deputy Director/Head, Yaba Laboratory

“The DG has demonstrated a rare quality in transition programmes. She did not only encourage the continuity of International Atomic Energy Agency (IAEA) programmes, but strongly supported the programmes morally, financially and administratively. This resulted in the completion of pesticide residue and pesticide formulation laboratories, veterinary drug residue laboratory and mycotoxin laboratory, with impressive training of high quality and specialized laboratory staff. The schedule of activity also resulted in the gazetting of food irradiation regulation in the Federal Government Gazette of Nigeria. This exemplary work shows that continuation of development programmes with International agencies is possible in Africa and the DG NAFDAC has demonstrated a commendable and exemplary way forward for other countries to emulate in the sub-region and in Africa in general.”

Pharm. Ibrahim Ali, Deputy Director Special Duties/Baseline Studies

“I was transferred from NAFDAC Inspectorate Office, Port Harcourt, Rivers State to Technical Services Unit in the office of the Director General in Abuja in February 2002. During this time, the Agency was being re-structured and re-organised by management to enable it carry out its functions effectively. From 2002 to date, I have worked as Head of FCT NAFDAC office, Officer in charge of Technical Service Unit, Officer in charge of Pharmacovigilance Unit and presently, I am the Deputy Director in charge of Baseline studies/ Special duties Office, Abuja. These units are all in the Director General’s office.

The privilege of working in these units and reporting directly to the Director-General provided me the opportunity to learn and acquire some unique attributes of Prof. Dora N. Akunyili, OFR. These attributes include transparency, honesty, humility, fairness, accountability, equity, hardwork, administrative and technical competence, fear of God Almighty and the drive to achieve excellence with available human and material resources.

Working directly with the Director General also has its challenges. These include measuring up to technical/administrative standards required for effective regulatory functions and working extra hours to accomplish assigned tasks.

Prof. Akunyili encouraged training and re-training of officers. The training equipped officers at state and zonal levels to perform their regulatory functions effectively and adequately represent NAFDAC at important functions in their respective areas of operation.

I am indeed very grateful to be among those that are privileged to work directly under Prof. Dora N. Akunyili OFR.”

Dr Matty Udoe, Personal Assistant to Director General on Special Duties

“I have closely worked with Prof. Dora Akunyili, Director General NAFDAC, from April 2001 till date as her Personal Assistant on Special Duties in our Lagos office. During this period, I have represented her at over 300 public functions and received over 100 awards on her behalf.

The incidence of fake, counterfeit and substandard drugs which became noticeable in Nigeria in 1968, worsened progressively until Dora came in April 2001 as Director General of NAFDAC. Within 4 years into the fight, Dora recorded remarkable success in reducing counterfeit medicines prevalence in Nigeria from 41 per cent to 16 per cent.

What marvels me most about the woman is her no nonsense style of doggedness and determination to stamp out counterfeit medicines in Nigeria. This is a woman that transformed pressure into a sense of urgency in addressing the counterfeit medicines problem. She believes that everyone has an opportunity to build a good reputation, touch the hearts of others and leave a positive footprint in the sandstones of time. Her closeness to God is so alarming that even after the assassination attempt on her life, she pursued her fight against counterfeit medicines so vigorously as never done before and this made her more credible in the eyes of the public.

In addition to the fact that Dora gets on very well with people, she is very humble, very kind, very compassionate, gentle, respectful, honest, diligent, transparent, accountable and very hardworking.

Prof. Dora Akunyili has inspired me a lot. She taught me how to make honesty a habit, have a sense of purpose in everything I do, be courageous, show absolute commitment and care to mankind and remember that a good name is better than silver and gold. Dora is an icon, a success, a living legend and above all, a beacon of compassion, hope, peace, progress and love. I will forever love to work with her.”

Mr I.S. Adamu, Chief Regulatory Officer, NAFDAC Maidugiri

“Working with the Director General NAFDAC has been full of experiences and a source of joy. One thing that is ever fresh in my memory was the concern she showed to me when I came under pressure from Drug hawkers in Gombe and Borno States. She took time out of her tight schedule to come to Gombe and Maiduguri to express her dismay to the authorities concerned. Her concern for our plight has been our source of inspiration and a morale booster that is propelling us to work extra hard towards realizing the mandate of NAFDAC. Indeed she is an epitome of integrity and an apostle of hard work.

Unlike during the previous administration, there is clear manifestation of the fight against counterfeit medicines in reality within and outside the shores of Nigeria.

Prof. Akunyili runs an open door policy administration, where every staff has a stake on topical issues without fear of victimization. With her leadership, the last 7½ years has witnessed fair training opportunities and local manufacturers have received the highest support. Indeed NAFDAC has become a household name within and outside Nigeria.”

Mr. Benson Kine, Zonal Head, NAFDAC Special Zonal Office, Onitsha

“Under Prof. Akunyili’s leadership, I have had the opportunity of working in challenging places such as Aba and Onitsha. I was in Onitsha during the closure of the famous Bridge Head Drug Market and fully participated in the exercise. My working under a dynamic and fearless leader like the present Director General has inculcated in me the spirit of fearlessness as long as I am doing the right thing. Under her, the fight against counterfeit medicines has been more focused, dogged and aggressive. I have enjoyed motivation that has enhanced my performance under the erudite Professor. Throughout my 19 years of working until the present management came in, I have never had an opportunity of travelling outside the shores of Nigeria, but now I have travelled more than once, due to her fair and equal treatment of all staff members.

Another significant area of difference between NAFDAC before 2001 and now is the provision of office infrastructure, funds and staff training for the war against counterfeit medicines. These and others have resulted in the success story as recorded today. I have indeed imbibed the culture of hatred for counterfeit medicines from the present DG and promise to continue the fight until total victory is achieved.”

Pharm. B.A. Yusuf, Chief Regulatory Officer, Abuja Inspectorate

“Prof. Dora Nkem Akunyili (OFR) is my mentor in many respects. Her irrevocable dedication to safeguard the health of Nigerians by ensuring that only quality or wholesome, efficacious and safe regulated products are made available to the public has been my guiding principle to put in my best since I was employed in 2002. I always view her with full admiration and copied her style of leaving no jobs pending. This has been the secret of achievements recorded in EID–FCT Office since I was posted there in August, 2005.

Prof. D. N. Akunyili is an agent of God for human salvation, not only in NAFDAC, but also in providing jobs for the hopeless, for which I am a beneficiary. I recall precisely on April 21st, 2002 at about 8p.m. when I walked to her office with an application letter as I was jobless. She graciously employed me, as Assistant Chief Regulatory Officer. This miraculous feat happened after I had lost hope and never thought it was still possible for me to secure employment with the Federal Government, having graduated as a pharmacist from Ahmadu Bello University, in 1983.

Honesty, transparency and absolute dedication to duty have been my dreams in life. These I could not achieve in my 17 years sojourn in private establishments. This icon of hope, Prof. Dora N. Akunyili, has however, tutored and mentored me to achieve these dreams.

Our prayer is that we get to where our parents could not in life and this was fulfilled in my life through the continuous, genuine and transparent staff motivation instituted by the Director General to reward hardworking staff. I benefited from this strategy immensely as I have been trained and travelled to many continents of the world.

It is on record that institutionalization of NAFDAC enlightenment campaigns created under the dynamic leadership of Prof. D. N. Akunyili, has turned regulatory activities into a household name in Nigeria. It cannot be over emphasized that Prof. Dora N. Akunyili has laid unparalleled regulatory legacy for Nigerians in NAFDAC.”

Mr Gabriel Agbator, Chief Regulatory Officer/Unit Head, Imo State

“Prof. Akunyili’s strategy of involving the general public and thus making the fight against counterfeit medicines a national issue, was, in my opinion, the greatest singular weapon against counterfeit medicines in Nigeria. Through serious enlightenment programmes, NAFDAC was able to rouse public consciousness and interest to the extent of mobilizing Nigerians to join in the fight against the hydra-headed monster. In this crusade, the

involvement and corporation of the Nigerian public in all segments of the society (government, foreign embassies, stakeholders, households, students, workers, the common man, etc.), provided the greatest encouragement, impetus and lever for the resounding success in the war against counterfeit medicines. This strategy was weak or non-existent before 2001. Positive behavioral and attitudinal change on the part of NAFDAC workforce was another source of strength in the crusade by Prof. Dora Akunyili. She has truly done marvelously well.”

Mrs Josephine Abbas Dayilim, Unit Head, Plateau State

“Prior to 2001, Nigeria was a dumping ground for fake and counterfeit drugs. This resulted in the springing up of illegal drug markets and chaotic drug distribution channels. However, since the appointment of Prof. Dora Akunyili as Director General of NAFDAC in April 2001, the incidence of fake and counterfeit drugs has reduced drastically following her vigorous and determined approach to the war against the fake drug merchants.

Prof. Akunyili has brought honour to the Agency and country through her dogged fight against fake and counterfeit drugs, which earned her many awards and recognitions locally and internationally. The Agency’s dislodgement of the drug cartels made them to fight back using threats, intimidation and physical attacks on officers culminating into a shooting attack on our dear Director General. We were undaunted and with God on our side, the war on counterfeit medicines is being won! We will not stop until counterfeit medicines are completely eradicated in our dear country. May God continue to bless Prof. for bringing sanity to an abused drug regulatory environment through her exemplary leadership, thereby saving millions

Mr Eruaga Michael Alurame, Senior Regulatory Officer, NAFDAC

“I started working directly with Prof. Dora N Akunyili in July 2006. I assisted her in writing some of her speeches. Initially, it was work non-stop and I found it very difficult to adjust to her undying desire for work. However, as time passed by, I learnt to be patient and now I can match her unending desire for work and perfection. Working with her has greatly exposed me. It has taken me to parts of the world where I never thought of going to at this stage of my life. Apart from my personal gains, it is worthy for me to say that Prof. Akunyili’s leadership style is exceptionally outstanding and excellent. She is transparent, just, fair and incorruptible. These are qualities, which are rare among Nigerian leaders today. I believe that if Nigeria had three more of Prof. Akunyili, we would have achieved our 2020 vision and would now occupy our rightful place of pride among other nations of the world.

Prof. Akunyili is a success driver. I have no regrets working with her.”

The Humorous Side of Hard Work

The enlightenment campaigns brought us so much success that a NAFDAC registration number was sought for every item, even when such products were not regulated by NAFDAC. A typical incident happened in Enugu where the police stopped a motorcyclist popularly known as Okada on a routine check for the particulars of the motorcycle. The police found some tools on him and demanded to see the NAFDAC registration number. It created a scene; upon release from his “captors”, the Okada man raced to the people he had purchased the tools from to demand the NAFDAC registration numbers, only to be told that those products did not have NAFDAC registration numbers because they are not regulated by NAFDAC.

Another funny incident involved my brother’s new nanny who has never been to school and therefore, could neither read nor write. He gave her a pack of orange juice but she put it away and left it untouched for three days on top of the refrigerator. When asked why she did not drink the juice, she replied “Oga, omego expire” which means, “master it has expired” and that was why she did not drink it. My brother wondered aloud how she could have known that the drink had expired. She said that she gave it to the security guard whom she learnt had primary education, to read, and he told her that although the juice had a NAFDAC registration number, it had expired and this was why she did not drink it! My brother was forced to apologise to her for giving her expired juice, though unknowingly.

It has become a standing joke at Nigerian functions for people to ask for the NAFDAC registration number of everything served, including cakes! People even ask me whether they have NAFDAC registration numbers as individuals and I always jokingly reply that they should ask their spouses who would be in the best position to certify them!

EXAMPLES OF CARTOONS ON NAFDAC FROM SOME NATIONAL DAILIES

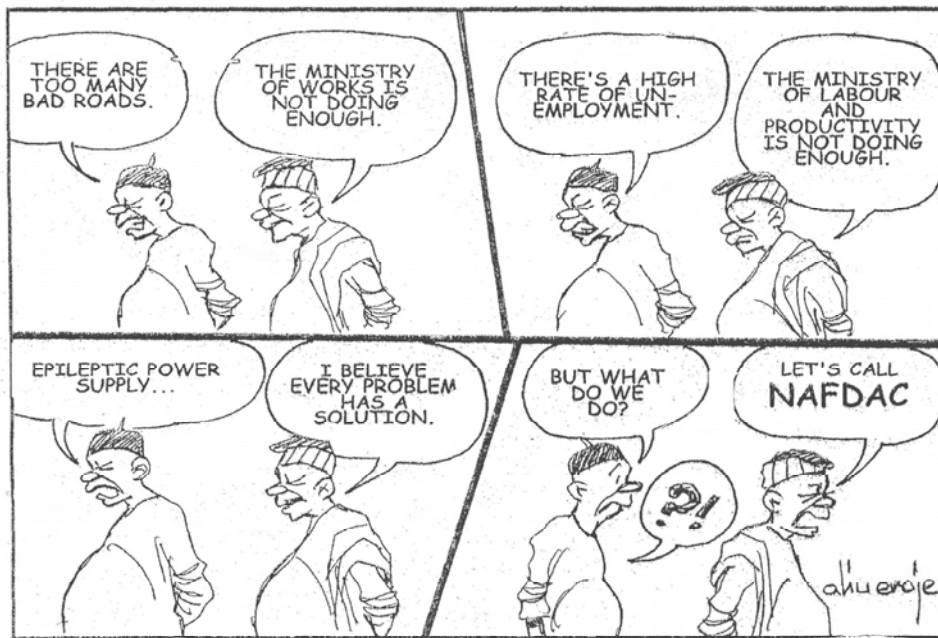


Figure 32: The Punch newspaper July 14, 2008



Figure 33: *The Nation* newspaper – September 20, 2008

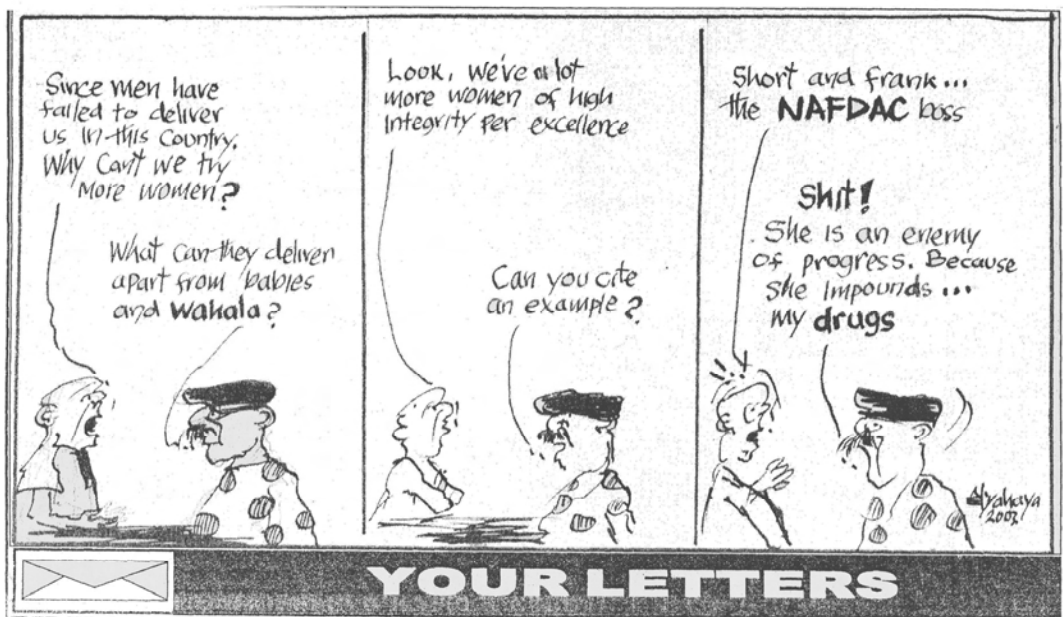


Figure 34: *The Daily Trust* newspaper – September 19, 2003

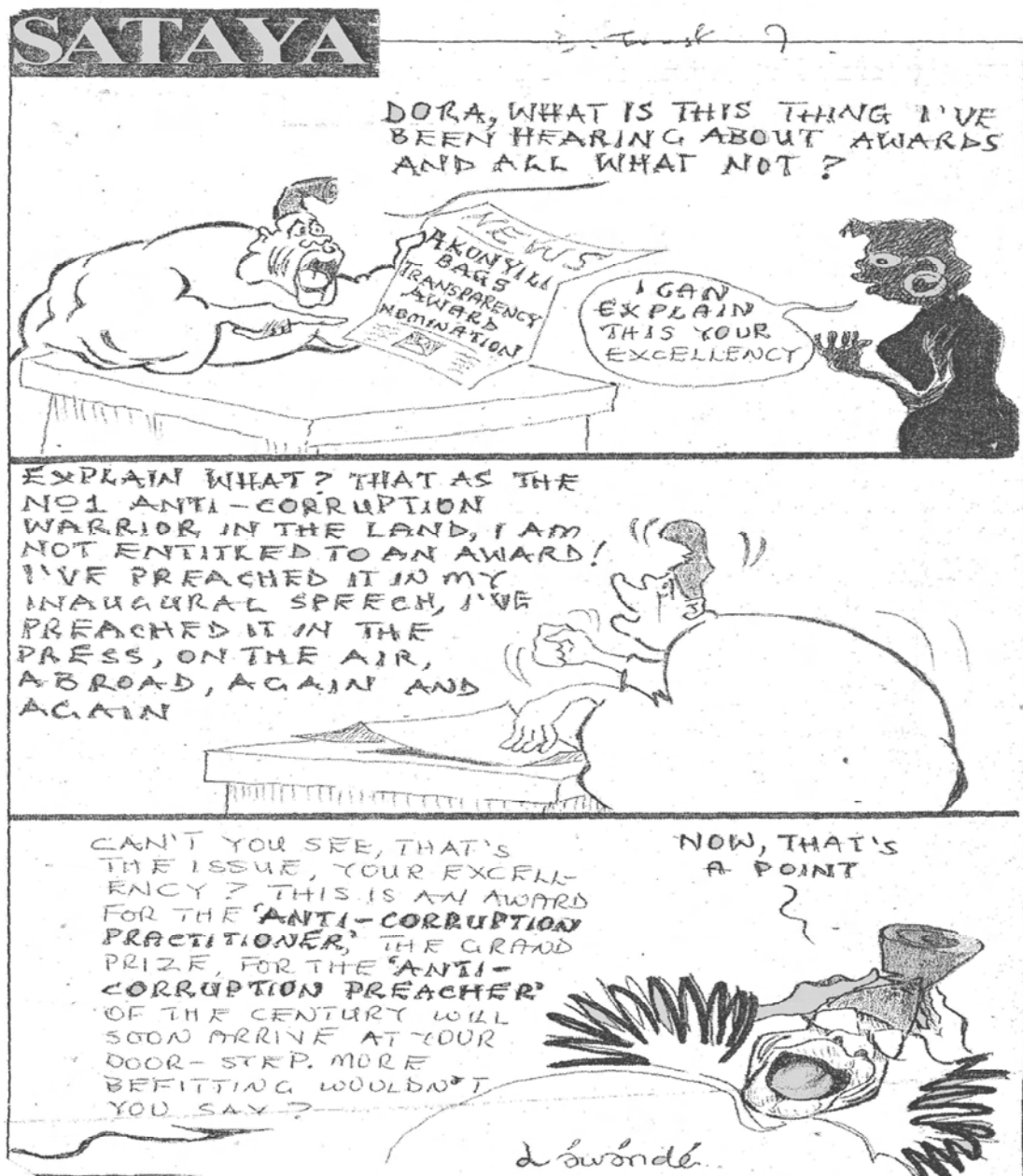


Figure 35: *The Daily Trust* newspaper – May 12, 2003



Figure 36: The *Daily Times* newspaper April 23, 2004

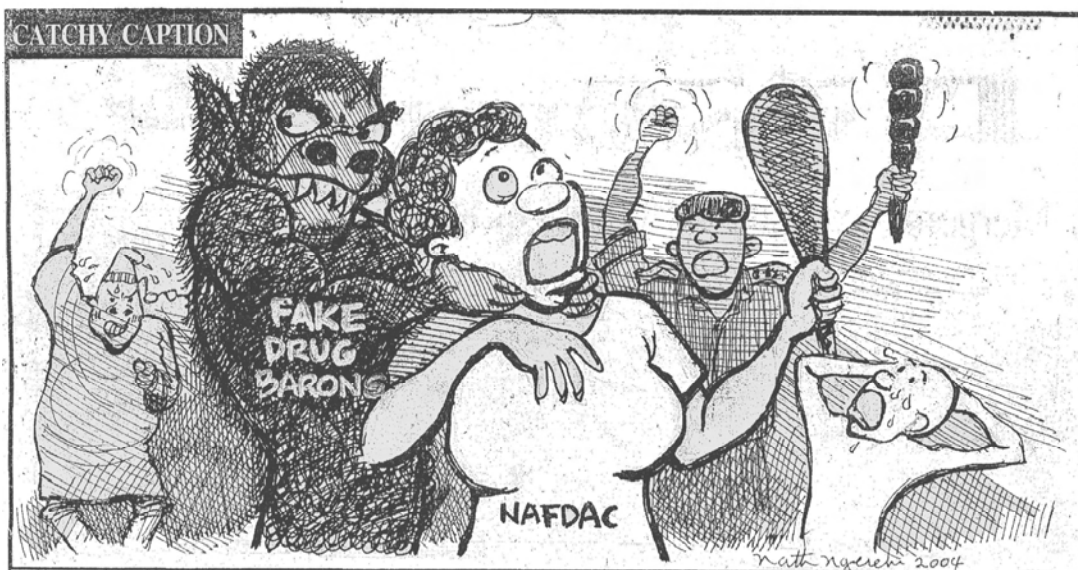


Figure 37: The *Vanguard* newspaper – April 26, 2004

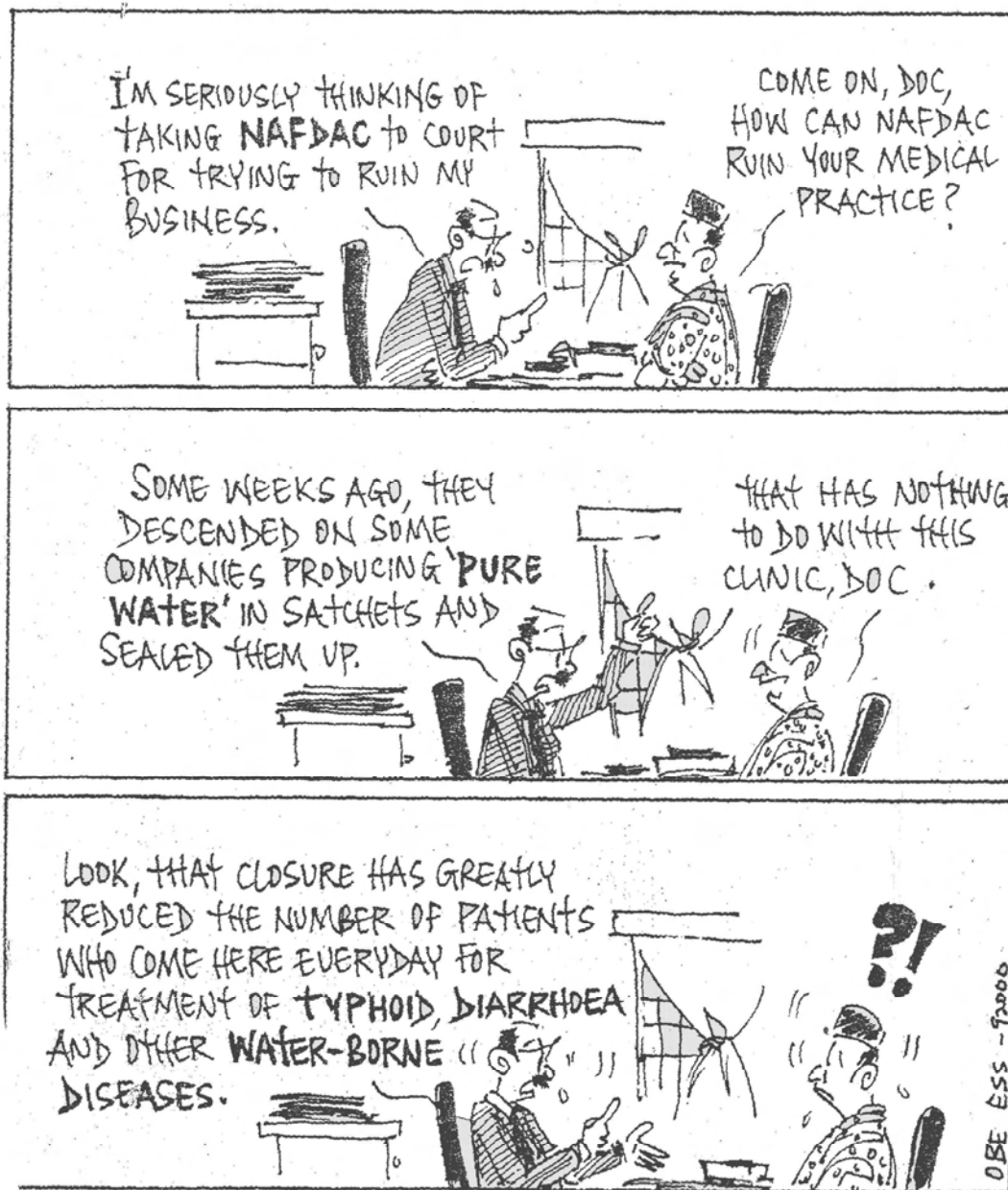


Figure 38: *The Guardian* newspaper – February 7, 2005



Figure 39: *The Vanguard* newspaper – May 19, 2005



Figure 40: *The Daily Sun* newspaper – December 17, 2008

CHAPTER 18

FUTURE PLANS/WORK IN PROGRESS RECOMMENDATIONS AND CONCLUSION

Future Plans

In charting a new course for the future, NAFDAC should consolidate on its present gains, work towards surmounting all outstanding constraints, improve on its administrative and operational capacities and explore new approaches to enhance efficiency and effectiveness. To achieve this, there is the need to consider the following critical areas:

Regular Interaction with Stakeholders

In addition to consolidating and continuing with the ongoing interactions with various stakeholders through workshops, seminars, meetings, etc, NAFDAC should extend these interactions to every Local Government Area in Nigeria in its grassroots sensitisation campaign. At one point, plans were under way for a workshop for Local Government Chairmen from the 774 Local Government Areas across the country. We had a meeting with the President of the Association of Local Governments of Nigeria (ALGON), Chief Bayer Dzeremo, in July, 2006. The plans did not materialise due to logistical reasons. More aggressive campaigns are required for chemical marketers to prevent the re-occurrence of tragedies such as the My Pikin incident.

Laboratories

The establishment of mini-laboratories at all designated ports of entry for on-the-spot testing to detect counterfeit medicines and other substandard regulated products, must be pursued vigorously. When fully implemented, this will reduce the delays in the current practice of sending samples from the ports to various laboratories for full analysis, since only products or raw materials which require further testing, would be delayed and sent to the laboratories.

We had concluded plans to buy field testing kits from Mr Tom Woods of Woods International in collaboration with Ahura Scientific, USA. We were at the stage of making payments when I left NAFDAC. Our other plans included the establishment of laboratory facilities of

international standards in all the geopolitical zones of the country and new specialised laboratories, such as a Biochemical Laboratory, to enhance NAFDAC's ability to collaborate effectively with relevant international organisations, such as the United Nations Office of Drugs and Crime.

There must be a strategic plan to develop expertise in the detection of Genetically Modified Foods, regulation of the irradiation of food and the expansion of facilities for the detection and quantification of contaminants, bacteriological typing (such as *Listeria*, *E. coli* 0157), Mad Cow Disease (BSE) detection, Dioxins & PCB detection and Immuno Assay Techniques.

It has been proposed that NAFDAC's laboratories should serve as reference laboratories in the West African sub-region, in collaboration with IAEA, the WHO, FAO and other relevant international organisations. This is a huge opportunity that must be driven to a logical conclusion.

Registration and Regulatory Affairs

There is the need to fully computerise and streamline NAFDAC registration and other processes, to further reduce the turn-around time to the barest minimum. Specifically, NAFDAC should fully implement the SIAMED computer network programme for drug registration, as recommended by the WHO.

Providing Security Features to Safeguard Regulated Products

The development of tamper-proof security systems for the protection of NAFDAC's regulatory instruments, such as registration numbers, receipts, certificates, staff identity cards and permits was NAFDAC's priority. The Agency explored various product security options, including the use of tamper-evident holograms for regulated products. NAFDAC is already using holographic labels to protect its certificates and other sensitive documents. We also set in motion a series of processes and initiatives to achieve the use of a serialised holographic label option on all NAFDAC registered products, starting with medical products, to secure the registration numbers in order to prevent them from being faked. These serialised holographic labels, which are in use in many countries, are powerful anti-counterfeiting devices. Given Nigeria's situation and desperate attempts by drug counterfeiters to continue to circumvent the law and NAFDAC's efforts, the use of holograms is the most viable option. In the process of planning for the working of holographic labels in Nigeria, two NAFDAC staff were sent to Malaysia to study the use of this device for two weeks. Thereafter, we held meetings with various stakeholders on the modalities for the

implementation in which we had reached an advanced stage. We also commenced discussions with M-Pedigree of Ghana for the use of an SMS messaging system in cross-checking the NAFDAC registration number of registered products. They commenced discussions and negotiations with PMG–MAN at our instance. We believe that it will take off before the holographic labelling system, because of its simplicity and affordability. Furthermore, the drug manufacturers felt more comfortable with the SMS system, as soon as we introduced it to them.

Operational Networking

NAFDAC should pursue the development of a functional and effective information management system for better coordination of the activities of the Agency. We planned to complete the networking of NAFDAC operations in the states, zones and headquarters, to facilitate the free and timely flow of information and access to databases on NAFDAC activities and operations. This will include the establishment of functional and state-of-the-art data banks and documentation centres and the development of reliable databases for drug storage, distribution, sale and use. An earlier planned completion of this phase in our progressive development plan was forestalled by the violent burning down of our facilities in 2004.

Food and Drug Training Institute

We proposed to establish a self-funding food and drug training institute, with the initial funding to be provided by NAFDAC. The institute would train NAFDAC staff, government inspectors and analysts. It would also serve as a training centre for all food and drug regulatory agencies in West Africa. We already have land for this project in Kaduna state, Nigeria.

Improving National and International Collaboration

We planned to further strengthen our national and international collaboration with other regulatory and similar agencies, for enhanced effectiveness. This collaboration has definitely begun in many areas and needs to be improved. One vital area in international collaboration from which NAFDAC has benefited is information sharing, which has enabled us to regularly receive very useful alerts from other countries. An example was an alert we received from Germany, regarding the bid by a company in Nigeria to import Ephedrine from Germany. The Nigerian company had fraudulently altered the quantity of Ephedrine approved for them in their import permit, increasing it by over 2,500 per cent, from 20kg to 520kg! Our prompt response to the relevant German authorities, indicating that we did not approve the

importation of such a large volume of Ephedrine, ensured that the fraud was nipped in the bud.

At the national level, we received an alert in June 2008 from the National Intelligence Agency (NIA), indicating that a suspicious brand of mosquito coil was in circulation in the markets. Although the brand of coil had been duly registered by NAFDAC, the batches circulating in the markets were toxic and unregistered. Mosquito coils are on the Federal Government's import prohibition list. The untested batches of the mosquito coil were removed from the markets to avert the serious health problems that could arise from their use.

Improved Staff Welfare

We proposed to sustain employee commitment through staff motivation and appropriate incentives, such as an enhanced salary scale. We reached an advanced stage of employing many more staff in accordance with due process. We also reached an advanced stage in working out an improved salary scale and the approval process was at the final stage.

Expansion of Operations

Many of NAFDAC's state offices are operating from rented accommodation. We planned to build our own offices in such states. To this effect, we have secured land from some State Governors. Gombe State is an example, where Governor Danjuma Goje gave us a strategically placed piece of land in the state capital, free of charge. We also planned to open mini NAFDAC offices in every Local Government Area in Nigeria. We need to establish NAFDAC offices in the port towns of Burutu, Koko and Bomadi and at the land borders of Mfun in Cross River State and Jibiya in Katsina State to enhance effective supervision. I hope that NAFDAC will be better funded to accomplish this dream.

Other Goals

- a) Strengthening of staff capacity, through training and re-training of staff in regulatory control and management functions. This is in keeping with the high premium NAFDAC places on staff development.
- b) Strengthening of the National Pharmacovigilance Centre to enhance drug safety monitoring, as well as the monitoring of other regulated products.

- c) Providing more incinerators to prevent the problems encountered during destruction exercises, such as scavenging, pollution of the environment and poorly managed dumpsites. Though some incinerators were provided for NAFDAC by the Federal Ministry of Environment, we could not put them to use because they did not have the required capacity to destroy large quantities of drugs.
- d) Encouraging job rotation, whereby technical Directorate staff will be reshuffled once every three or four years, to eliminate monotony on the job. This will also present staff members with new challenges, which is expected to enhance productivity.
- e) Training of staff of the Enforcement Directorate in security and self-defence. This will increase their effectiveness in enforcement activities and reduce their apparent vulnerability and dependence on the police to provide security. We had commenced discussions on this with GSK.
- f) Strengthening of post-marketing surveillance activities to guarantee the sale of only genuine registered regulated products in Nigeria.
- g) Continuous review of Standard Operating Procedures (SOPs), guidelines and checklists to incorporate new ideas. This will improve communication between NAFDAC and its clients and amongst NAFDAC staff themselves.
- h) Strengthening of the Food and Drug Information Centres and the establishment of Zonal and State Centres.
- i) Regulation of the control of advertisement of drugs, especially herbal medicines. This is an area where, I feel, we did not record much success despite all our efforts.
- j) Extension of the drug abuse seminars and enlightenment campaigns conducted in schools to work places, for civil servants in both rural and urban areas and for factory workers.
- k) Harmonisation of the control of chemicals with other agencies, such as the Federal Ministry of Environment, the Federal Ministry of Agriculture and the NDLEA.
- l) Strengthening the monitoring of importation, distribution, storage, sale and utilisation of narcotics, psychotropic and precursor chemicals and general chemicals nationwide.
- m) Provision of a list of all chemical marketers nationwide, including their products and locations and dismantling of illegal chemical outlets.

- n) Ensuring the enactment and amendment of various NAFDAC draft bills already forwarded to the National Assembly.
- o) Inclusion of members of the Legal Unit in the Codex Alimentarius Commission and World Trade Organization.
- p) Continuing the advocacy for an international convention on counterfeiting of pharmaceuticals.
- q) Encouraging private organisations to establish zonal drug distribution centres, also known as Drug Marts as the surest way to sanitise the chaotic drug distribution system in Nigeria.

In recognition of the fact that in the delivery of healthcare services, quality of products and services cannot be compromised, as people's lives are involved, we should continually borrow best practices from around the world and combine them with our ideas, in order to develop the most effective regulatory system for Nigeria. To this end, NAFDAC should follow global trends in product regulation, while consolidating on our present strategies, which have proven to be very effective. The Agency should also continue to involve its stakeholders and consumers in formulating strategies for future challenges. Establishing greater control on the supply chain will be an integral part of the anti-counterfeiting strategy, especially in the area of control of product flow, inspection, better security features and authentication. We hope to realise our goals to such an extent that our slogan, NAFDAC: **Safeguarding the Health of the Nation**, will ring true.

RECOMMENDATIONS

I highly recommend that organisations, irrespective of constraints, should strive to perform their functions by exploiting their potentials and expanding existing administrative capacities. Transparency, forthrightness and leadership by example are the most important tools for fighting any form of corruption. The most effective strategy in the war against fake/counterfeit drugs is public enlightenment, which sensitises the public on the evils of counterfeit medicines and the necessity to eradicate them. In this way, public support and confidence are harnessed, without which corruption cannot be stamped out.

From my NAFDAC experience, corruption in the health sector is surmountable, in spite of the extensive criminal network of the perpetrators. All countries must pay adequate attention

to corrupt tendencies, such as drug counterfeiting and put in place effective sanctions to deter these merchants of death from engaging in such heinous crimes.

The practice of exporting spurious products to other countries is antithetical to human dignity. The United Nations and the entire international community must adopt a more proactive approach in addressing the issue of counterfeiting of pharmaceuticals.

I strongly advocate for an international convention against counterfeiting of pharmaceuticals, just as we have for Narcotics and Psychotropic substances. This will ensure harmonised regulation of pharmaceutical products moving in international commerce.

We need a World Health Assembly (WHA) resolution, making it mandatory for member countries to assure the quality and safety of products being exported to other countries. Exporting countries must ensure that the quality of medicines for export is not only subjected to the same standards as those for domestic use, but the quality should also meet internationally accepted standards.

The eradication of counterfeit drugs should be treated as an International Health Emergency Programme. All forms of criminal networks, especially drug counterfeiting networks, must be dismantled at individual, industrial and government levels. The staff of drug regulatory authorities found engaging in corrupt practices should be severely sanctioned, while hardworking and honest workers should be adequately rewarded. Individuals or corporations caught in drug counterfeiting should be severely dealt with, without fear or favour. Laws against drug counterfeiting should be deterrent enough to make the business unattractive. The least punishment, as we recommended to the Nigerian National Assembly, should be life in jail without any option of a fine.

Pharmaceutical manufacturers should collaborate with the regulatory authorities, improve in-house checks and security and carry out regular market surveillance on their products. They should put in place anti-counterfeiting measures, like holograms, marks and special inks, to safeguard their products. Manufacturers should have effective consumer complaint units and an efficient drug recall system.

Healthcare providers are advised to order their drugs from reputable sources, dispense drugs only from original packs and report any suspected counterfeit product. Wholesalers are advised to apply Good Distribution Practice (GDP) and collaborate with regulators in carrying out their activities.

Above all, there is the need for a comprehensive communication strategy to provide robust public enlightenment campaigns on the health care challenges in developing countries such as Nigeria.

CONCLUSION

The regulatory process is complex and expensive. It is therefore difficult for developing countries, especially those in Africa, to effectively protect themselves from the influx of fake and counterfeit drugs. Our vision was to reduce the incidence of fake/counterfeit drugs and other substandard regulated products to the barest minimum within the shortest possible time and to become a model regulatory Agency in Africa.

The counterfeiting of pharmaceuticals is a global problem. It is rapidly rearing its ugly head even in developed countries, fuelled by the purchase of drugs via the Internet. The negative impact of counterfeit drugs knows no boundaries. Resistant strains of micro-organisms induced by substandard antibiotics do not need a visa to travel from country to country. Drug counterfeiting involves transnational criminal networks which can only be dismantled through international collaboration. Collaboration among regulators, the police, customs and other stakeholders must be promoted. Regulators must work with confidence knowing that criminals have no power over them as long as they are not compromised. Counterfeiters can be overcome despite the daunting constraints, as evidenced by our successes in Nigeria.

My NAFDAC experience shows that any moribund organisation can be revived with the right strategies, determination to succeed and support. Despite all the difficulties, dangers and threats I encountered in evolving a new NAFDAC, I was convinced that, with determination and hard work, we would succeed, and to a large extent, we did. We drastically reduced the level of incidence of fake/counterfeit drugs in Nigeria and we expect to see almost complete eradication in the near future, so that we can hand over to our children a country free of counterfeit medicine.

I am concluding this book in December 2008 because President Umaru Musa Yar'Adua has appointed me Nigeria's Minister of Information and Communications effective December 18, 2008. In this new position with wider responsibilities, I look forward to putting in my best once again in the service of my country. I pray that successive NAFDAC administrations will build on the formidable structures we have put in place, and the processes that have been institutionalised over the years. I look forward to the realisation of the many plans we have set in motion.

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ABBREVIATIONS

ABU	-	Ahmadu Bello University, Zaria
ACT	-	Artemisinin-based Combination Therapy
ADR	-	Adverse Drug Reaction
A&F	-	Administration and Finance
AGF	-	Accountant General of the Federation
ANOR	-	Another (party) (legal)
ANPP	-	All Nigerian People's Party
APIN	-	Association of Pharmaceutical Importers of Nigeria
BCG	-	Bacillus Calmette-Guerin
BMS	-	Breast Milk Substitutes
BP	-	British Pharmacopoeia
BPP	-	Bureau of Public Procurement
BSE	-	Bovine Spongiform Encephalopathy
CAFON	-	Consumer Advocacy Forum of Nigeria
CEO	-	Chief Executive Officer
cGMP	-	Current Good Manufacturing Practice
COPP	-	Certificate of a Pharmaceutical Product
CRIA	-	Clean Report of Inspection and Analysis
DD	-	Deputy Director
DFID	-	Department for International Development
DG	-	Director General
DPT	-	Diphtheria, Pertussis and Tetanus

EDM	-	Essential Drug Monitor
EID	-	Establishment Inspection Directorate
ELISA	-	Enzyme Linked Immunosorbent Assay
EMRC	-	European Market Research Centre
EOHSI	-	Environmental and Occupational Health Services Institute
EU	-	European Union
FAAN	-	Federal Airport Authority of Nigeria
FAO	-	Food and Agriculture Organization
FDA	-	Food and Drug Administration
FDAC	-	Food and Drug Administration and Control
FDF	-	Federal Department of Fisheries
FDIC	-	Food and Drug Information Centre
FGN	-	Federal Government of Nigeria
FHC	-	Federal High Court
FIP	-	Federation Internationale Pharmaceutique (International Pharmaceutical Federation)
FIRS	-	Federal Inland Revenue Service
FPSN	-	Fellow of the Pharmaceutical Society of Nigeria
FRN	-	Federal Republic of Nigeria
FSA	-	Food Standards Agency, United Kingdom
FSH	-	Follicular Stimulating Hormone
GACG	-	Global Anti-Counterfeiting Group
GAIN	-	Global Alliance for Improved Nutrition
GC	-	Gas Chromatograph
GC/MS	-	Gas Chromatography/Mass Spectrometry
GLC	-	Gas Liquid Chromatograph

GLSI	-	Global Listing of Supermarket Items
GMO	-	Genetically Modified Organism
GCP	-	Good Clinical Practice
GDP	-	Good Distribution Practice
GMP	-	Good Manufacturing Practice
GPTC	-	General Purposes Technical Committee of the National Codex Committee
GSK	-	GlaxoSmithKline
GSM	-	Global System for Mobile
HACCP	-	Hazard Analysis and Critical Control Point
HBV	-	Hepatitis B Virus
HCG	-	Human Chorionic Gonadotrophin
HIV/AIDS	-	Human Immunodeficiency Virus/Acquired Immune Deficiency Syndrome
HPLC	-	High Performance Liquid Chromatograph
HPTLC	-	High Performance Thin Layer Chromatography
IAEA	-	International Atomic Energy Agency
ICCIDD	-	International Council for the Control of Iodine Deficiency Disorder
ICDRA	-	International Conference of Drug Regulatory Authorities
ICPC	-	Independent Corrupt Practices and Other Related Offences Commission
IECP	-	INFOSAN Emergency Contact Point
IMF	-	International Monetary Fund
INCB	-	International Narcotics Control Board
INFOSAN	-	International Food Safety Authorities Network
IPMIN	-	Indian Pharmaceutical Manufacturers and Importers in Nigeria

KLT	-	Kirikiri Lighter Terminal
LH	-	Luteinizing Hormone
LUTH	-	Lagos University Teaching Hospital
MCA	-	Medical Control Agency
MI	-	Micronutrient Initiative
MOU	-	Memorandum of Understanding
MSG	-	Monosodium Glutamate
NAFDAC	-	National Agency for Food and Drug Administration and Control
NARPAD	-	NAFDAC Registered Products Automated Database
NARTO	-	National Association of Road Transport Owners
NBA	-	Nigerian Bar Association
NCS	-	Narcotics and Controlled Substances
	-	Nigerian Customs Service
NDDC	-	Niger Delta Development Commission
NDLEA	-	National Drug Law Enforcement Agency
NFRAC	-	National Food Risk Analysis Centre
NGO	-	Non-Governmental Organisation
NHIS	-	National Health Insurance Scheme
NIFST	-	Nigerian Institute of Food Science and Technology
NIPRD	-	National Institute for Pharmaceutical Research and Development
NPA	-	Nigeria Ports Authority
NPC	-	National Pharmacovigilance Centre
NPI	-	National Programme on Immunisation
NSE	-	Nigerian Stock Exchange
NTA	-	Nigeria Television Authority

NURTW	- National Union of Road Transport Workers
ODC	- On-duty Cards
OFR	- Order of the Federal Republic
OPPMDU	- Onitsha Patent and Proprietary Medicine Dealers Union
OPV	- Oral Polio Vaccine
OTC	- Over-the-counter
PABX	- Private Automatic Branch Exchange
PATHS	- Partnership for Transforming Health Systems
PCB	- Polychlorinated biphenyl
PCN	- Pharmacists' Council of Nigeria
PDP	- People's Democratic Party
PID	- Ports Inspection Directorate
Plc.	- Public Limited Company
PMG-MAN	- Pharmaceutical Manufacturers Group of the Manufacturers Association of Nigeria
PPMD	- Patent and Proprietary Medicine Dealers
PRS	- Planning, Research and Statistics
PSI	- Pharmaceutical Security Institute
PSN	- Pharmaceutical Society of Nigeria
PTF	- Petroleum (Special) Trust Fund
PVG/FDIC	- Pharmacovigilance/ Food and Drug Information Centre
QCS	- Quality Consultancy Services
RA	- Regulatory Affairs
RASFF	- Rapid Alert System for Food and Feed
RIA	- Radio-Immuno Assay
RIVM	- National Institute for Public Health and the Environment

R&R	-	Registration and Regulatory
Affairs SACAIDS	-	Save Africa Congress
for AIDS SAN	-	Shipping Association of Nigeria
	-	Senior Advocate of Nigeria
SAP	-	Structural Adjustment Programme
SGD	-	Single Goods Declaration
SIAMED	-	Sistema de Informacion Automatizada sobre Medicamentos
SON	-	Standards Organisation of Nigeria
SOP	-	Standard Operating Procedure
SPS	-	Sanitary and Phytosanitary
TB	-	Tuberculosis
TI	-	Transparency International
TMP	-	Traditional Medicine Practitioner
UCH	-	University College Hospital, Ibadan
UNDCP	-	United Nations Drug Control Programme
UNICEF	-	United Nations International Children's Education Fund
UNN	-	University of Nigeria, Nsukka
UNTH	-	University of Nigeria Teaching Hospital, Enugu
USAID	-	United States Agency for International
Development USFDA	-	United States Food and Drug Administration
USI	-	Universal Salt Iodisation
USP	-	United States Pharmacopoeia
VAT	-	Value Added Tax

WADRAN	-	West African Drug Regulatory Authorities Network
WAN	-	Wide Area Network
WARPH/PRSAO	-	West African Regional Programme for Health/ Programme Régional Santé en Afrique de l'Ouest
WASC	-	West African School Certificate
WHA	-	World Health Assembly
WHO	-	World Health Organization
WHT	-	World Holding Tax
WIPO	-	World Intellectual Property Organization
WTO	-	World Trade Organization
ZDDC	-	Zonal Drug Distribution Centre

APPENDICES

APPENDIX 1: Commendation letter from Ex- Head of State, General Mohammadu Buhari



**PETROLEUM (SPECIAL)
TRUST FUND**

ZONE II HEADQUARTERS:
1 IDIMMBI DRIVE,
OFF EZIHO STREET,
INDEPENDENCE LAYOUT,
P.M.B. 01560 ENIGI.
TEL: 042 - 458871 FAX: 042 - 454900

10th February, 1999.

The Executive Chairman,
PTF,
Airport Road,
Abuja.

Your Excellency,

LETTER OF APPRECIATION/REPORT OF MY MEDICAL TRAVEL

Words cannot adequately express my deep sense of appreciation for your kindness in approving my medical trip. The only way I can express my health condition after the extensive tests and treatments is that I never knew I can ever feel so well. I very humbly enclose Dr. Konotey's report cum attachments minus radiology reports (because they are on large thick sheets and will not be easy to handle).

You may recall, Sir, that I was given £5,100 for diagnostic tests and £12,000 for surgery and hospitalization. As God would have it, by the time the doctors finished with extensive tests and various therapies, they concluded that surgery was unnecessary (Refer to Dr's reports page 2b, 22 and 23b). The extra money I got from the £5,100 after paying for tests and doctors' consultations was enough to take care of drugs and my living expenses (which was minimal because I spent the 23 days with a family).

The £12,000 for surgery was therefore returned by the hospital and I hereby return it with heart full of joy and gratitude.

Most respectfully yours.

DNAKUNYILI
Dora Akunyili

Zonal Secretary Zone II.

DD(T)/DA/22

*We discuss the at a signed
the issue the location of
as in lieu of hotel accommodation*

*See that there are still Nigerian in
Personal integrity.
Please take action in line with
TF financial regulations
10/02*

DF

*See above report from PTF
Zonal Secretary Zone II.*

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APPENDIX 2–NAFDAC Laws

1. Food and Drugs Act (Cap 150) of 1990 (formerly called Food and Drugs Decree No. 35 of 1974). This law repealed state laws in operation at the time with respect to food and drugs. It provided among other things that no one was permitted to sell adulterated food or drugs or food unfit for human consumption or any cosmetic which if used according to instructions on the label would cause damage to the users' health. Another highlight of this law was that it provided for the appointment of inspecting officers who had the power to enter any premises where violative drugs, food or cosmetics were suspected to be kept.
2. Food and Drugs Act (Amendment) Decree No. 21 of 1999, replaced the Food and Drugs Act (150) of 1990. It amongst other things made it an offence for anyone to tamper with or interfere with the "Hold" label placed on any premises or article by an inspecting officer. It further increased the maximum fine payable on conviction for the contravention of the law from ₦1,000 to ₦50,000 (US\$8 to US\$420).
3. National Agency for Food and Drug Administration and Control Decree No. 15 of 1993 - this is the law that dissolved the Food and Drug Administration Department of the Federal Ministry of Health and in its place established NAFDAC. The powers, structure and functions of NAFDAC are enumerated in the law. It also provides that none of the Agency's assets may be attached by a court order. It states also that anyone whose premises are entered further to this law is under obligation to assist the NAFDAC officials in carrying out their duties.
4. National Agency for Food and Drug Administration and Control (Amendment) Decree No. 19 of 1999, amends the National Agency for Food and Drug Administration and Control Decree No. 15 of 1993. It, amongst other provisions, increased the maximum fine payable for obstructing NAFDAC officials in the performance of their duties from ₦5,000 (US\$42) to ₦50,000 (US\$420). It also makes corporate entities culpable and liable to be fined ₦100,000 (US\$835) if found guilty of the same offence.
5. Drugs and Related Products (Registration etc.) Decree No. 19 of 1993 makes it unlawful to deal in unregistered drugs. It also states the requirements for the registration of drugs with NAFDAC and conditions under which a NAFDAC

certificate of registration may be withdrawn, suspended or cancelled. Clinical trials are to be carried out only on obtaining a valid clinical trial certificate and following strictly the terms of that certificate. A convict under this law will be liable to a fine not exceeding ₦50,000 (US\$420) or to imprisonment for a term not exceeding two years or to both such fine or imprisonment. For a body corporate, they are liable to be fined not more than ₦100,000 (US\$835).

6. Drugs and Related Products (Registration etc.) (Amendment) Decree No. 20 of 1999 amends Drugs and Related Products (Registration etc.) Decree No. 19 of 1993 among other things provided that anyone convicted under this law will also be liable to forfeit not only instruments used in committing the offence but will also forfeit any asset or property obtained as a result of the offence.
7. Counterfeit and Counterfeit medicines (Miscellaneous Provisions) Decree No. 17 of 1989, prohibited dealing in counterfeit, fake, adulterated or banned drugs and poisons. It set up the Task Forces at Federal and State levels.
8. Counterfeit and Counterfeit medicines and Unwholesome Processed Foods (Miscellaneous Provisions) Decree No. 25 of 1999 repealed the Counterfeit and Counterfeit medicines (Miscellaneous Provisions) Decree No. 17 of 1989. This is presently the most effective law in terms of deterrent. A convict under this law may be asked to pay a maximum fine of ₦500,000 (US\$4,170) or be sentenced to a prison term of between five and 15 years. It targets not only principal offenders but persons who aid or abet the crime. This is a vast improvement from the provisions of the repealed law which stipulated that this class of offenders could not be fined more than ₦5,000 (US\$42). A convict is liable to forfeit the offending products to the government.

APPENDIX 3 – Old Regulations

The laws governing the operations of NAFDAC empower the Agency to make regulations for effective and efficient performance. This entails the compilation of technical details and scientific standards of all products regulated by NAFDAC in order to ensure the safety of the products for the benefit of the citizenry.

Fourteen regulations gazetted by NAFDAC between 1993 (its inception) and April 2001 (beginning of the new administration) are as follows:

1. NAFDAC Tariff Charges Regulations 1994 provided for charges in respect of services rendered by the Agency.
2. Drug Products Advertisement Regulations 1995 seek to control the advertisement of both prescription and over-the-counter drugs. An application for the approval of a drug advert shall contain amongst other things a justification for any special claims on the drug.
3. Pre-Packaged Food (Labelling) Regulations 1995 provide for the appropriate labelling of prepackaged foods by including date markings, batch number and prominently declaring any nutritional claims.
4. Cosmetics (Prohibition of Bleaching Agents) Regulations 1995 prohibit the use of bleaching agents such as Hydroquinone, Corticosteroids, Mercury compounds and other bleaching agents in body creams.
5. Bottled Water (Advertisement) Regulations 1995 provide that all advertisements for bottled water must be as approved by NAFDAC and shall be accurate and clear.
6. Non-Nutritive Sweeteners in Drug products (Prohibition) Regulations 1996 prohibited the use of non-nutritive sweeteners in drugs, but provided that NAFDAC could permit their use in special dietary conditions.
7. Pesticide Registration Regulations 1996 provide that all pesticides shall be registered with NAFDAC and all applications shall clearly state the composition of such pesticides and their environmental impact.
8. Food Products Registration Regulations 1996 outline the requirements for registration of food or food products. They also state the grounds on which a certificate of registration may be suspended, withdrawn or cancelled.

9. Non-Nutritive Sweeteners in Food Products Regulations 1996 prohibit the use of non-nutritive sweeteners in food products, which include food/beverages presented for infants' and children's consumption. They could, however, be used in special dietary foods/beverages such as energy reduced foods/beverages.
10. Food Products (Advertisement) Regulations 1996 provide that only food products registered by NAFDAC can be advertised. Such advertisements must be pre-cleared and approved by NAFDAC. Misleading statements such as false value claims must not be contained in the advertisement.
11. Food Grade (Table or Cooking) Salt Regulations 1996 prescribed the standard for food grade (Table or Cooking) salt. Labels are required to ensure a clear distinction between industrial salts and those intended for human consumption.
12. Bottled Water (Registration) Regulations 1996 provide that every bottled water shall be registered with NAFDAC.
13. Bottled Water (Labelling) Regulations 1996 prohibit the sale of unlabelled bottled water. In addition the label must contain date markings and batch number, as well as the name and address of manufacturer.
14. Cosmetics and Medical Devices (Advertisements) Regulations 1996 provide that all cosmetics products and medical devices must be registered by NAFDAC before advertisement.

APPENDIX 4 – Functions of NAFDAC Directorates

Director General's Office

The Director General's Office has ten units.

- i. Lagos Office
- ii. Special Duties
- iii. Technical Services Unit
- iv. Public Relations Unit
- v. Legal Services Unit
- vi. Internal Audit Unit
- vii. Baseline Study Unit
- viii. Maintenance/Transport Unit
- ix. Computer Unit
- x. Pharmacovigilance/ Food and Drug Information Centre (FDIC)

Finance and Accounts Directorate

The Finance and Accounts Directorate of NAFDAC was created from the Finance and Administration Directorate in August, 2008. This followed a directive from the office of the Head of Service of the Federation, that all finance and administration Directorates in government ministries and parastatal be split into the Administration Directorate and the Finance and Accounts Directorate.

The Directorate coordinates the general day-to-day financial activities of the Agency and advises management on the most prudent ways to utilise available funds. The responsibilities of the Directorate include among others, the control of the Agency's expenditure. This entails preparation of non-staff payments, processing of VAT and WHT in respect of non-staff payments, processing of imprests to state/zonal offices, processing touring and purchases advances and raising journals for final accounts. It is also responsible for the preparation and payment of staff salaries, registration and processing of all staff claims, processing payment of retired staff pensions and liaison with the Salaries & Wages Commission.

Another major function of the Finance and Accounts Directorate is management of the Agency's treasury. This includes collection and banking of the Agency's revenue, maintenance of Cash Books of outstations, remittance of VAT deductions to FIRS and liaising with Agency's bankers.

The Finance and Accounts Directorate is responsible for preparing and defending the Agency's budget. It monitors and evaluates the implementation of the budget and liaises with the Budget Office, Ministry of Finance, Ministry of Health and the National Assembly on financial matters. The Directorate also processes contractors' registration, tenders, Due Process Certification and liaises with BPP and AGF, on Due Process Matters.

Furthermore, it is responsible for keeping records of the Agency's assets, maintaining the fixed assets registers, disposal of assets as approved by management and maintenance of store records and the Agency's supplies.

Administration Directorate

Just like the Finance and Accounts Directorate of NAFDAC, the Administration Directorate was created from the former Finance and Administrations Directorate in August, 2008, following the same directives. The Administration Directorate focuses on general administrative and human resources activities of NAFDAC. It ensures that personnel matters, such as promotion, discipline and payment of emoluments are effectively implemented and sustained. The Administration's Directorate carries out appointments in NAFDAC and ensures that competent manpower and appropriate staff members are available to accomplish the mandate of the Agency.

It conducts statutory promotion exercises for eligible staff members and also handles issues relating to transportation, security, sanitation, staff welfare (NHIS, NHF, Pension Matters, insurance, etc.). It also maintains the secretariat for the Agency's Governing Council/Board.

Planning, Research and Statistics (PRS) Directorate

The PRS Directorate is the service Directorate responsible for planning, research and data collation for the Agency. It coordinates and documents the various activities of other Directorates. The Directorate is responsible for the development of plans for the Agency, the monitoring and evaluation of programmes, projects and plan implementation, provision of secretariats for senior management meetings, collation and processing of data relating to the Agency's mandate and manpower training and development including workshops, conferences and seminars. The Director of PRS supervises the two divisions in the

Directorate, Planning, Monitoring and Training (PMT) and Research and Statistics (RS). A Deputy Director or Chief Regulatory Officer heads each of the divisions.

Narcotics and Controlled Substances Directorate

This Directorate ensures that Nigeria, through the operations of NAFDAC, fulfils her obligations under the relevant international treaties and conventions by the effective monitoring of the licit use of regulated drugs and chemicals. The functions of the Directorate include the control of importation of narcotic drugs, psychotropic substances, controlled chemicals and weapon precursors through various permits and licences. The Directorate also inspects and monitors the use of narcotic drugs and other controlled substances for which permits have been issued, collects data on controlled substances and submits returns to the International Narcotics Control Board (INCB) and the United Nations Drug Control Programme (UNDCP). It also coordinates enlightenment and education activities on drug abuse and consultative meetings with stakeholders. A Director supervises the four divisions in the Directorate: Narcotics Control, Drug Abuse, Chemical Monitoring and Chemical Control/Permit. Each division is headed by a Deputy Director or Chief Regulatory Officer.

Registration and Regulatory Affairs (R&R) Directorate

The R&R Directorate registers products and prepares draft regulations and guidelines for regulatory activities. The directorate's functions include registration of all regulated products, updating and formulating relevant regulations, control and monitoring of product advertisements, receiving and investigating consumer complaints and organising meetings with stakeholders. A Director supervises the four divisions in the Directorate: Food, Drugs, Regulatory Affairs and Advertisement Control. A Deputy Director or Chief Regulatory Officer oversees each division.

Establishment Inspection Directorate (EID)

The EID was created from the former Inspectorate Directorate by the new administration. The EID inspects local establishments engaged in the manufacture, storage, distribution and sale of regulated products to ensure that only products duly registered by NAFDAC are in circulation. The Directorate's functions are the routine monitoring and inspection of establishments, pre-production and production inspection of establishments, pre-registration inspection, surveillance inspection, investigation inspection, sanction activities and consultative meetings with stakeholders. A Director supervises the activities of the ten special zonal offices each of which is headed by a Deputy Director or a Chief Regulatory

Officer. The zonal head coordinates inspection activities of all the state offices in each zone. Each state office is headed by an officer of the rank of Senior Regulatory Officer or above.

Ports Inspection Directorate (PID)

The Ports Inspection Directorate (PID) monitors the passage of regulated products in all ports of entry (sea, air and land border post) to ensure that only registered regulated products are imported and exported. The PID has offices at the sea ports and airports, Seme and Idiroko Border Posts, and inland container terminals. Its other basic functions include screening of import documents before the issuance of pre-release stamps, inspection of imported regulated products at the ports of entry before release, bonding of unregistered regulated products for mandatory registration and release, issuance of export certificates (combined certificate of manufacture and free sales) and Certificate of Pharmaceutical Products (COPP), and carrying out joint inspection and sampling of sea food products intended for export with officials of the Federal Department of Fisheries (FDF).

Laboratory Services (LS) Directorate

The Laboratory Services Directorate carries out all functions relating to analytical quality control of all regulated products, to ascertain their quality before and after registration and in accordance with good laboratory practices. Their major activities include laboratory testing, lot release, sampling of food and drugs and validation of equipment and test methods. The Directorate analyses and pronounces on the quality and safety of regulated products and serves as a reference laboratory for other government agencies. A Director oversees the seven laboratories located in Kaduna, Yaba, Oshodi, Maiduguri, Port Harcourt, Calabar and Agulu. A Deputy Director supervises each laboratory.

Enforcement Directorate

The newly created Enforcement Directorate carries out enforcement activities. It harmonises the activities of other technical directorates on all substandard regulated products for appropriate compliance directives or sanction. The Directorates' specific functions are surveillance activities, special investigations, destruction exercises, enforcement of sanctions, collaborating with the legal unit for the prosecution of court cases and coordination of various associated task forces. A Director supervises the activities of the two divisions of Food and Drugs and a Deputy Director heads each division.

APPENDIX 5 – Regulations Put in Place from 2001 to November 2008

1. Drug Labelling Regulations 2005 provide that all relevant information be reflected on the product label and the leaflet inserted, so as to properly guide patients and healthcare professionals on the use of drugs. It also requires the express declaration on the labels that the product contains non-nutritive sweeteners.
2. Non-Nutritive Sweeteners in Drug Product (Prohibition) Regulations 2005 repealed the Non-nutritive Sweeteners in Drug Products (Prohibition) Regulations of 1996. The Penalty section was expanded to cover corporate bodies.
3. Herbal Medicines and Related Products (Registration) Regulations, laid down for the first time the procedure to be followed in applying for the registration of herbal medicines in Nigeria and made it an offence to deal in any unregistered herbal product.
4. Herbal Medicines and Related Products (Labelling) Regulations 2005 prohibit dealing in herbal medicines that are not properly labelled. They seek to control the high incidence of false claims about the potency of such medicines.
5. Herbal Medicines and Related Products (Advertisement) Regulations 2005 provide that no person shall advertise registered herbal product(s) without pre-clearance and approval of the Agency.
6. Pesticide Registration Regulations 2005 repealed the Pesticide Registration Regulations of 1996. The penalty section was expanded to include corporate offenders and provided for the forfeiture of any materials used in the commission of the offence.
7. Pre-packaged Food (Labelling) Regulations 2005 repealed the Pre-packaged Food (labelling) Regulations 1995 and provide that there must be express justification of any nutritional claims on the label. They expand the penalty section to include corporate entities and provide that offenders forfeit materials used in the commission of the offence.
8. Food Grade (table or cooking) Salt Regulations 2005, repealed the Food Grade (table and cooking) salt Regulations of 1995 and make non-compliance an offence.

9. Food Products (Advertisement) Regulations 2005 repealed the Food Products advertisement Regulations of 1995 and provide for the confiscation and destruction of foods that contravene the Law.
10. Food Fortification with Vitamin A Regulations 2005 stipulates that it is an offence to sell or advertise any food not fortified with Vitamin A. It is also an offence not to state on the label the quantity of Vitamin A present in the food.
11. Food Fortification Regulations 2005 specify minimum quantities of vitamins, minerals and micronutrients to be incorporated into food products. It further stipulates the mandatory registration of such products.
12. Cocoa Products Regulations 2005 make it an offence to deal in unregistered cocoa products or to use certain kinds of chemicals to process them without disclosure on the label. They provide standards for the identification of cocoa products and also specify the maximum level of additives.
13. Fats and Oils Regulations 2005 make it an offence to deal in fats and oils that do not have the prescribed level of Vitamin A fortification or are not registered with NAFDAC. They provide standards for the identification of fats and oil products and also specify the maximum level of additives and contaminants allowable in fats and oil products.
14. Milk and Dairy Products Regulations 2005 make it unlawful to deal in milk and dairy products not registered with NAFDAC. They provide standards for the identification of various dairy products. The source or mammal from which a milk or dairy product is obtained has to be declared on the label.
15. Soft Drinks Regulations 2005 identify the different classes of soft drinks and specify the minimum material composition for each class.
16. Wine Regulations 2005 mandate that all wines must be registered. They also list the different classes of wine and their contents and provide that wines can only be advertised in the media after clearance by NAFDAC.
17. Fruit Juice and Nectar Regulations 2005 define the compositions of fruit juice, nectar and fruit puree. They further stipulate that fruit juice containing non-nutritive sweeteners must be approved by the Agency.
18. Spirit Drinks Regulations 2005 stipulate that labels of all spirit drinks must state the actual percentage by volume of absolute alcohol they contain. In addition to the

standards for identification, this regulation also prohibits the advertisement of spirit drinks on children's programmes. The use of children, sportsmen and expectant mothers as models of advertisement is also prohibited.

19. Marketing of Infants and Young Children's Food and other Designated Products Regulations 2005. This is the first time a Nigerian legislation has captured the international code on marketing of breast milk substitutes (BMS) and the subsequent resolutions of the World Health Assembly. The regulations are meant to protect, promote and sustain breast-feeding and discourage unwholesome marketing strategies by manufacturers and distributors of BMS.
20. Food Additives Regulations 2005 ensure that food additives are used within stipulated limits so as to control the long-term cumulative effect of these substances, especially hepatotoxicity, carcinogenicity and such other outcomes.
21. Processed Food Registration Regulations 2005 list the documentary requirements for the registration of processed foods and provide that all processed foods for human consumption must be registered with NAFDAC.
22. Food Irradiation Regulations 2005 seek to preserve nutrients in food, control pathogenic organisms within acceptable limits and protect consumers from food poisoning. The quantity of radioactive emissions is also controlled under these regulations.
23. Cosmetics (Prohibition of Bleaching Agents) Regulations 2005 repealed the Cosmetics Products (Prohibition of Bleaching Agents, etc.) Regulations 1995 and now allow the inclusion of Hydroquinone in cosmetic products not beyond the internationally acceptable standard of 2 per cent.
24. Cosmetic Products (Labelling) Regulations 2005 provide for adequate labelling of cosmetic products in line with international regulatory requirements.
25. Food (Handling and Hygiene) Regulations 2008 are drawn from the CODEX text of food hygiene practices and encourage the local application of international food handling and hygiene standards.
26. Malt Drinks (Labelling) Regulations 2008 address the regulatory requirements for the manufacture, importation, advertisement and sale of malt drinks in Nigeria, including labelling requirements.

27. Cassava and Cassava Products Regulations 2008 clarify the minimum quality requirements for cassava and cassava products. Instructions for preparation and inclusion of food additives in cassava are also addressed in these regulations.
28. Pre-packaged Water Regulations 2008 establish the minimum requirements for the packaging of water for consumption. Emphasis is on sachet water. Microbiological and chemical limits are specified.
29. Pre-packaged Animal Feeds Regulations 2008 specify limits on food additives that should be used and maximum limits of contaminants, pesticide residues and veterinary drug residues in animal foods. They also require that a list of ingredients used in preparing animal feeds and directions for consumption should be stated on the label.
30. Chemical and Chemical Products Regulations 2008 specify basic scientific education for handlers of chemicals in commercial quantities. They further require that labelling of chemicals and chemical products (including cautions) be done in local Nigerian languages.
31. Permitted Colours Regulations 2008 seek to enforce the local application of international requirements for permitted colouring agents in regulated products.
32. National Agency for Food and Drug Administration and Control Tariff Charges Regulations 2001 repealed the Tariff Regulations of 1994. They increased the tariff payable to NAFDAC for services rendered, consequently increasing her revenue base.

REGULATIONS IN DRAFT

1. Drug and Drug Products (Registration, Sales, etc.) Regulations specify the required documents for drug products' registration. They further provide for the categorisation and re-categorisation of drug products based on new knowledge.
2. Donated Drug and Related Products seek to discourage dumping of drug products in the country and take into account the WHO guidelines on drug donations. Demands for donated drugs must be initiated from the health facility requiring donation and not from donors who are seeking to offload obsolete or about to expire drugs.
3. Orphan Drugs Regulations define orphan drugs for the purpose of ensuring availability and affordability.

-
4. Vaccines, Biologicals, Blood and Related Blood Products Regulations establish guidelines for the evaluation by NAFDAC of vaccines, biologicals and related products.
 5. Nutrition Claims and Foods for Special Dietary Uses Regulations seek to ensure the declaration of quantities of ingredients for special groups. They also take into account food allergies.
 6. Pasta Products Regulations establish the standards of identity for pasta products, including composition and limits of permitted food additives.
 7. Sugar and Sugar Products Regulations specify the quality factors for sugar as well as the maximum level of allowable contaminants.
 8. Wheat Flour Regulations establish the standards of identity for wheat flour and the requirements for fortification.
 9. Garri Regulations specify acceptable species of cassava that can be used as raw materials for Garri. Different types of Garri are also listed.
 10. Honey (Registration, etc.) Regulations specify the sources, types, definition and composition of honey.
 11. Beer Regulations provide a standard of identity for beer, ale, stout and lager produced as a result of fermentation of barley malt, sorghum malt or other cereal grains or starch hops or hop derivatives with potable water, with other suitable ingredients in such a manner as to possess the aroma, taste and character commonly attributed to each type. They may also contain additives.
 12. Good Clinical Practice Regulations seek to ensure that equity, justice and respect for the human participant/subject in clinical trials is upheld according to the Helsinki declarations of the World Medical Association and other declarations that border on the development of the human genome.

APPENDIX 6a Press Release on Packaged Water

**NATIONAL AGENCY FOR FOOD DRUGS
ADMINISTRATION AND CONTROL** CORPORATE

HEADQUARTERS

Plot 1057, Ikeja Crescent, Off Oyo Street Area II, Section 1, Garki, Abuja.

Tel: 09-234680-3 Fax: 09-2346382

As a follow up to NAFDAC nation wide workshop organised last year for all packaged water producers, those who still experience any form of problem in registering their products are hereby invited to report to the following centres on the 29th of April 2002 by

11am Prompt.

Please come with all relevant documents to help us identify and solve your problems.

Full enforcement activities will commence **ONE (1) MONTH** after this last exercise. You are therefore advised to use this last opportunity to ensure that your water is tested, found fit and registered.

S/N	ZONE	VENUE
1	North Central - Jos	Conference Hall, Federal Secretariat Complex, Jos
2	North West - Maiduguri	NAFDAC Laboratory Complex, Biu Road, Maiduguri
3	North West - Kano	Conference Hall, Federal Secretariat Complex, along Airport Road, Kano
4	South East- Enugu	Conference Hall, Federal Secretariat Complex, Independence Layout Enugu
5	South West - Ibadan	Conference Hall, Federal Secretariat Complex, Ibadan
6	South South - Port Harcourt	Conference Hall, Federal Secretariat Complex, Aba Road Port Harcourt

*Please help us to help you, so that together we
shall safeguard the health of our people* **Signed
management**

**NAFDAC: Safeguarding the health of the
Nation**

APPENDIX 6b – Public Notice to All Sachet Water Producers on Shelf Life of Sachet Water



**NATIONAL AGENCY FOR FOOD AND
DRUG ADMINISTRATION AND CONTROL**

CORPORATE HEADQUARTERS
Plot 2032, Olusegun Obasanjo Way, Wuse Zone 7, Abuja. Tel: 09-6709887, 09-5240995-6

PUBLIC NOTICE

TO ALL SACHET WATER PRODUCERS

Further scientific studies carried out by NAFDAC have shown that the 3 months shelf life generally allowed sachet water producers is no longer feasible because of our peculiar climatic conditions. The study showed that sachet water starts deteriorating a few weeks after production and becomes unfit for human consumption after 2 months.

NAFDAC therefore directs that all sachet water (not bottled water) should bear a shelf life of 2 months and the product label must have the following information:-

NAFDAC REGISTRATION NUMBER
BATCH NUMBER
PRODUCTION DATE
BEST BEFORE DATE

This directive takes effect from January 2nd, 2004

After January 2nd, 2004, any sachet water that bears more than the permitted two months shelf life will be confiscated, destroyed and the owner prosecuted.

NAFDAC: Safeguarding the Health of the Nation

Signed
MANAGEMENT

APPENDIX 7 – Public Apology by Marcel Nnakwe



MARCEL PHARMACEUTICAL CHEMISTS LTD.

Importers, Exporters, Representatives, Wholesales.
Retail and Dispensing Chemists.

Director / Managing
Chief Sir M. O. Nnakwe

BANKERS:
First Bank (Nig) PLC.
Bright Street, Onitsha,
Nigeria.

PHONE:
046: 411579
046: 411127
046: 216329

CORRESPONDENCE OFFICE:
17 Palmer Street,
P. O. Box 3349
Onitsha - Nigeria.
Fax : 056282015
Mobile Phone - 090501300

E-mail Marcel PHONE @ hot mail. Com.

Our Ref _____ Your Ref _____ Date 14th July, 2001.

THE DIRECTOR GENERAL,
N A F D A C.

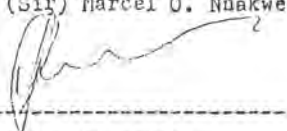
APPOLOGY FOR THE IMPORTATION OF FAKE, COUNTERFEIT AND EXPIRED DRUGS
INTO NIGERIA

Chief Marcel Nnakwe and ~~my~~ Family hereby apologise to NAFDAC, AND THE GOOD PEOPLE OF THIS Nigeria for Importing Fake, counterfeit and expired drugs into this Country.

I promise that I will never again involve myself in this illegal business. I also advise all that were in this ~~naferior~~ activity of dumping poison fake drugs into this Country to desist from this destardly action.

The Government of President Olusegun Obasanjo is very serious about deloting Nigeria from the list of countries where fake, adulterated substandard, expired and about to expire drugs and food substandard are dumped.

Chief (Sir) Marcel O. Nnakwe.


Managing Director.

APPENDIX 8 – Letter of Undertaking by Marcel Nnakwe



MARCEL PHARMACEUTICAL CHEMISTS LTD.

Importers, Exporters, Representatives, Wholesales,
Retail and Dispensing Chemists.

BANKERS:
First Bank (Nig) PLC.
Bright Street, Onitsha,
Nigeria.

Director/Managing
Chief, Sir M. O. NNAKWE

PHONE:
046: 411579
046: 411127
046: 216329

CORRESPONDENCE OFFICE:
17 Palmer Street,
P. O. Box 3349
Onitsha - Nigeria.
Fax : 056282015
Mobile Phone - 090501300

Our Ref.....

Your Ref

Date 14th July, 2001

THE DIRECTOR GENERAL,
N A F D A C.,
GARKI,
ABUJA.

Dear Ma,

LETTER OF UNDERTAKING NEVER TO IMPORT DISTRIBUTE
OR SELL FAKE EXPIRED SUBSTANDARD UNREGISTERED
PHARMACEUTICALS /

I hereby undertake not to import, distribute or sell fake, expired, substandard unregistered Pharmaceutical, in Nigeria.

I have made this solemn declaration this day for the good of all of us.

Thank you for this opportunity.

Yours faithfully,

Chief (Sir) M. O. Nnakwe.



Directors:- Chief Sir M. O. Nnakwe (Managing) Emmanuel Nnamdi, Nnakwe, P. N. Amobi (Mrs)-Pharmacist

APPENDIX 9 – NAFDAC Public Alert on Sale of Drugs in Moving Vehicles

VANGUARD

NATIONAL AGENCY FOR FOOD AND
DRUG ADMINISTRATION AND CONTROL
CORPORATE HEADQUARTERS
Plot 2032 Olusegun Obasanjo Way, Wuse Zone 7 Abuja
Tel. 5240995-6 Fax 5240994



NAFDAC ALERT ON SALE OF DRUGS IN MOVING VEHICLES

NAFDAC has held several meetings with the **National Union of Road Transport Workers (NURTW)** the **Road Transport Employers Association of Nigeria** and other operators and owners of buses plying major highways in Nigeria. During such meetings the Agency asked them to help protect the health of Nigerians by stopping the sale of drugs in their buses. NAFDAC also wrote many reminders to these bus owners and operators.

Having educated them enough, and to stop further exposure of our people to avoidable hazards, NAFDAC has decided as follows:

1. **Defaulting buses shall be grounded and impounded until conclusion of investigation and prosecution, and**
2. **The drug hawker and the bus driver will be arrested and sanctioned in accordance with existing laws and regulations.**

NAFDAC is therefore alerting the public that any bus caught in any route in Nigeria will be grounded and the journey terminated at that point. The Agency is concerned at the inconvenience that passengers in such buses will suffer but we cannot sacrifice the health of Nigerians because of such inconvenience. Passengers are therefore called upon to stop every hawker selling drugs in buses or disembark from such buses in their own interest.

There will be no further notice from NAFDAC on when this impending action will commence.

NAFDAC: Safeguarding the Health of the Nation.

Signed
Management

APPENDIX 10a – Invitation to All Traditional Medicine Practitioners

**NATIONAL AGENCY FOR FOOD AND
DRUG ADMINISTRATION AND CONTROL**

CORPORATE HEADQUARTERS: Plot 1057, Ikeja Crescent, Off Oyo Street, Area 11, Section 1, Garki Abuja

Tel: 09 - 2346 380, 3

PUBLIC NOTICE**NAFDAC INVITES ALL TRADITIONAL MEDICINE PRACTITIONERS TO SUBMIT
THEIR HERBAL/ANIMAL/MINERAL/OTHER FORMS OF MEDICINES FOR DUE
REGISTRATION PROCESSES AND STOP FURTHER ADVERTISEMENTS
OF PRODUCTS/CURES WITHOUT DUE CLEARANCE FROM NAFDAC**

The National Agency for Food and Drug Administration and Control was established by Decree 15, 1993 (as amended) to control and regulate the manufacture, importation, exportation, distribution, advertisement, sale and use of food, drugs, cosmetics, chemicals, detergents, medical devices, and all drinks including our popular pure water.

It has come to the notice of NAFDAC that many ineffective and dangerous traditional medicines are being administered to unsuspecting Nigerians by some unscrupulous orthodox and unorthodox medical practitioners.

We have also taken note of many deceitful advertisements of drugs especially herbal preparations, that are claimed to have cure for all forms of diseases ranging from headache to HIV/AIDS.

Media organizations are kindly requested, for the good of all Nigerians, to ask their clients for authority from NAFDAC before they advertise any product. This is because no medicine (orthodox or unorthodox) is supposed to be advertised or administered without NAFDAC's approval.

NAFDAC by law, has to screen and authorize such advertisements before they go out to the public. Media houses should for the sake of dying Nigerians shun the money paid for such criminal adverts.

To this effect, the Agency hereby notifies all traditional medicine practitioners that all their herbal and other medicines intended for use in man or animals must be submitted for due Laboratory analysis and other registration processes, which may include clinical trials, within 30 days from the date of this publication.

Failure to meet this deadline will result in NAFDAC resorting to the relevant laws.

NAFDAC safeguarding the health of the Nation

**Signed:
Management**

APPENDIX 10b– Guidelines for Listing/Registration of Herbal Medicines**GENERAL RULES**

1. Herbal medicinal products to be considered for registration or listing may be categorised as

- (a) Herbal medicinal products manufactured locally.
- (b) Imported Herbal medicinal products.
- (c) Homeopathic herbal medicinal products.

The following guidelines do not apply to Extemporaneous preparations. These are preparations made by the practitioner and given to his/her patient on a one-to-one basis within the locality of its preparation.

The guidelines are for manufactured products that are intended for distribution outside the locality of production, that is, to very wide areas through other outlets and for storage for a considerable period of time. The preparation and shelf-life of the products are therefore significant.

2. It is necessary to emphasise that no herbal medicinal products and related products shall be manufactured, imported, advertised, sold or distributed in Nigeria, unless they have been registered in accordance with the provisions of Decree 19 of 1993 as amended by the accompanying guidelines.
3. Application for registration or listing of herbal medicinal products shall be on the prescribed application forms and would be considered separately and registered as such.
4. Any product whose name, package or label bears close resemblance to and/or sounds like an already registered/listed product or is likely to be mistaken for such registered/listed product shall not be considered for registration.

PROCEDURE FOR REGISTERING/LISTING OF HERBAL MEDICINAL PRODUCTS MANUFACTURED LOCALLY

Applicants/Manufacturers

- a. Applicants shall obtain an application form upon payment of the prescribed fees per product through bank draft in favour of the National Agency for Food and Drug Administration and Control (NAFDAC).
 - b. The applicants/manufacturers shall submit completed application forms with relevant documents viz.:
 - i. Certificate of Registration of Business.
 - ii. An acceptable certificate of analysis testifying that the medicine is of proven quality and safety from accredited centres recognised by NAFDAC.
 - iii. Appropriate Dossier Format (containing method of analysis or assay of the medicine, stability data etc.) for product to get registered/listed.
 - iv. Receipt of purchase of application form.
 - v. Any other relevant documents.
 - c. Pre-registration inspection shall be carried out on the production premises by NAFDAC Inspectors after payment of prescribed fees to assess Good Manufacturing Practice (GMP) standards.
 - d. If inspection is satisfactory, NAFDAC inspectors will collect samples for laboratory analysis.
 - e. All herbal medicinal products must be adequately labelled before samples are sent to the laboratory.
 - f. On receipt of a satisfactory laboratory report, the product is approved for listing. For full registration, satisfactory report of local clinical trials will be required.
- *Note that listing is for two (2) years period while registration is for (5) years.***
- g. All applicants/manufacturers shall pay the prescribed fee for registration/listing Certificate after approval.

- h. Applicants/manufacturers shall submit a mandatory post-marketing surveillance report on the use and adverse reactions of the herbal medicinal products to NAFDAC.

PROCEDURE FOR REGISTRATION/LISTING OF IMPORTED HERBAL MEDICINAL PRODUCTS

- a. In addition to General rules in the Registration/Listing of Herbal Medicinal products, the following documents are required for imported herbal medicinal products after obtaining the usual Application Forms upon payment of the prescribed fees.
 - i. Power of Attorney issued by the manufacturer and notarised by a notary public from the Country of Origin.
 - ii. Certificate of pharmaceutical production (COPP).
 - iii. Application for permit to import samples for registration/listing purpose.
 - iv. Evidence of satisfactory clinical trials conducted in the country of origin and/or any African Country.
 - v. Any other relevant information on the products
- b. Applicants shall submit dossiers containing relevant information on the products' format.
- c. Applicants of imported herbal medicinal products shall pay a prescribed fee for the issuance of an import permit through bank draft in favour of NAFDAC.
- d. If documents/dossiers are satisfactory, the applicants shall also pay a prescribed fee for laboratory evaluation.
- e. Overseas inspection of facilities/GMP will also be carried out on the premises of the manufacturer of herbal medicinal products by NAFDAC inspectors during processing of application.
- f. On receipt of satisfactory laboratory reports, the products may be approved for registration/listing.
- g. Applicants shall also pay prescribed fees for registration/listing Certificate after approval.

- h. A mandatory local clinical trial in an approval institution to be funded by the applicants/manufacturers must be carried out for full registration.

LABELLING REQUIREMENTS (LOCAL/IMPORTED)

The herbal medicinal preparations manufactured locally or imported to the country shall carry the following basic labelling information in English and may include other languages.

- 1 Name of the product (not suggestive of therapeutic claim).
- 2 Generic name if applicable.
- 3 Quantitative list of ingredients by their botanical or common names.
- 4 Dosage form and net contents in terms of weight/measure count.
- 5 Directions for use.
- 6 Indications (shall be on the leaflet). No claim of cure is permitted until proven through clinical trial. Also subject to advertisement regulations.
- 7 Batch number.
- 8 Manufacturing date.
- 9 Expiry date.
- 10 Special storage conditions.
- 11 Name and full location address of manufacturer.
- 12 Provision for NAFDAC registration number.
- 13 Dosage.
- 14 Mode of administration.
- 15 Duration of use (e.g. specify if expected response is not felt within a certain number of days consult your doctor).
- 16 Specific symptoms of overdose and antidote on the leaflet.

- 17 Contra-indications/drug interactions.
- 18 Warnings, if any.
- 19 Precautions (e.g. use in pregnant and lactating mothers not recommended).

HOMEOPATHIC MEDICINAL PRODUCT

A. Applicants shall submit the following:

- i. Name and full location address of applicants (Not P.O. Box).
- ii Name and full location address of premises for the production of the homeopathic medicinal products.
- iii. Site description, company profile and organogram.
- iv. Particulars and licence of premises used for manufacturing.
- v. Certificate of analysis for products.
- vi. Method of analysis of assay and reference standards used.
- vii. Stability data.
- viii. Dossier format of product.

B. Homeopathic Medicinal Products shall carry the following basic labelling information:

- i. Name of the product (not suggestive of therapeutic claim).
- ii. Quantitative list of ingredient(s).
- iii. Dosage form.
- iv. Directions for use (specify for children, elderly, etc.).
- v. Indications.
- vi. Dosage (if appropriate, specify for children and elderly).
- vii. Mode of administration.

-
- viii. Duration of use (e.g. specify if response expected is not experienced within certain number of days consult your doctor).
 - ix. Symptoms for overdose and what not to exceed.
 - x. Contra-indications.
 - xi. Warnings, if any.
 - xii. Precautions (e.g. use in pregnant and lactating mothers not recommended).
 - xiii. Batch number, manufacturing and expiry dates.
 - xiv. Full name and location address of the manufacturer.
 - xv. Special storage conditions, if any.
 - xvi. Provision for NAFDAC registration number.

APPENDIX 10c – Public Notice on Placement and Airing of Unauthorised Adverts on Drugs

**NATIONAL AGENCY FOR FOOD AND DRUG
ADMINISTRATION AND CONTROL (NAFDAC)****CORPORATE HEADQUARTERS**Plot 1057, Ikeja Crescent, off Oyo Street Area 11 Section 1, Garki Abuja
Tel: 09-234680 – 3 Fax: 09 – 2346382**PUBLIC NOTICE****PLACEMENT AND AIRING OF
UNAUTHORIZED ADVERTS ON DRUGS**

Despite the National Agency for Food and Drug Administration and Control's (NAFDAC) warning to media houses to shun unapproved advertisement of orthodox and herbal preparations, the Agency has observed with dismay, the flagrant violation of our country's laws by various media houses.

NAFDAC is empowered by Decree No. 15 of 1993 to regulate and control the manufacture, importation, exportation, **ADVERTISEMENT**, distribution, sale and use of food, drugs, cosmetics, water, chemicals, medical devices and detergents.

The Agency appreciates the invaluable role of all responsible media houses in the fight to eradicate fake and counterfeit drugs in Nigeria. However, we view with serious concern the indiscriminate publication of advertisements, on both the print and electronic media, on ineffective and dangerous orthodox and herbal drugs with false claims without NAFDAC approval. This is done against the provisions of the law that NAFDAC is empowered to enforce.

APPENDIX 10d – Edo State Bans State Broadcasting Station from Promoting Alternative Medicine without Permit from NAFDAC

Edo bans state broadcasting station from promoting alternative medicine

SUYI AYODELE, Benin

EDO State government has banned the state-owned broadcasting station from promoting tradi-medical practitioners in the state.

The state governor, Chief Lucky Igbinedion, issued the ban

on Friday while receiving the Director-General of the National Agency for Food, Drugs Administration and Control (NAFDAC), Dr. Dora Akunyili.

Governor Igbinedion, who called on the Federal Government to treat producers and vendors of

fake drugs as murderers, ordered the state broadcasting station to stop forthwith, the promotion of tradi-medical doctors who claimed to cure all ailments.

The governor appealed to individuals to consider the overriding interest of the general public in setting up their industries since the objective was to benefit the society.

Governor Igbinedion also called for adequate funding of research centres so as to bring about the needed developmental options in the health sector.

Speaking earlier, Dr. Akunyili said that the production and sales of fake drugs were not restricted to foreigners, adding that Nigerians were involved in the trade which had led to the death of many.

APPENDIX 10e – Request to State Governors for Ban on Unauthorised Advertisements of Herbal Medicines in their States

NATIONAL AGENCY FOR FOOD AND DRUG ADMINISTRATION AND CONTROL



NAFDAC CORPORATE HQ:
Plot 2032 Olusegun Obasanjo Way,
Zone 7, Wuse - Abuja.
Tel: +234-9-5240994
Tel/Fax: +234-9-5241461
E-mail: nafdac@nafdac.gov.ng
Website: www.nafdac.gov.ng

LAGOS LIAISON OFFICE:
Central Laboratory
No 5, Oshodi Apapa Expressway,
Near Oshodi Flyover, Lagos
Tel: +234-1-4731018
Tel: +234-1-4524259
Tel: +234-1-4521212
Tel/Fax: +234-1-4528031

Director-General

NAFDAC/DG/102/1/TS
24th July 2003

His Excellency
Dr. Orji Uzor Kalu
The Executive Governor of Abia State
Government House
Umuahia, Abia State

Your Excellency,

REQUEST FOR BAN ON ADVERTISEMENT OF HERBAL MEDICINES

The National Agency for Food and Drug Administration and Control (NAFDAC) established under decree No. 15 of 1993 as amended by decree No.19 of 1999 is a parastatal under the Federal Ministry of Health with the mandate to regulate and control quality standards of foods, drugs (orthodox and traditional), cosmetics, medical devices, chemicals and pre- packaged water and other regulated products imported, manufactured locally and distributed in Nigeria.

As your Excellency knows, the primary mandate of the Agency is to enhance the quality, safety and wholesomeness of regulated products in order to promote public health through the total eradication of fake and counterfeited drugs and other substandard regulated products in our country.

To achieve this mandate, it regulates and controls the manufacture, importation, exportation, advertisement, distribution, sale and other regulated products. It also conducts laboratory tests to ensure compliance with WHO and other standard specifications.

The Agency in its effort thus far, has achieved some successes. Nevertheless, a lot more still needs to be done. It is in these regards that I am constrained to write to your Excellency and solicit your kind support.

You may have noticed in recent times sir, that there has been a tremendous upsurge in media advertisements on herbal medicines, most of which have not been registered by NAFDAC. This scenario greatly undermines the efforts of the Agency in achieving an effective regulation of the use of herbal medicines and most importantly poses grave health risks to the populace.

In line with our resolve to safeguard the health of the nation, I appeal to your Excellency to use your good offices and ensure that the state media houses refrain from carrying advertisements on herbal medicines from henceforth. Only those herbal medicaments which have been duly registered by NAFDAC can be advertised. However, even for those, there must be a proof of official approval.

Let me put on record Sir, the Agency's appreciation of your immense support and encouragement in our effort to restore sanity in the Food and Drugs industry. Your support has really been a great source of inspiration to us. Please I urge you not to relent in your support, the task is not easy by any means.

Sincerely,
DNAkunyili
Prof. Dora N. Akunyili (OFR)
Director General

APPENDIX 11 – NAFDAC Red Alert, No.3 on Potassium Bromate

PAGE THIRTEEN

**NATIONAL AGENCY FOR FOOD AND DRUG
ADMINISTRATION AND CONTROL (NAFDAC)****CORPORATE HEADQUARTERS**

Plot 1057, Ikeja Crescent, off Oyo Street Area 11 Section 1, Garki Abuja
Tel: 09-234680 – 3 Fax: 09 – 2346382

NAFDAC RED ALERT, NO.3!

The National Agency for Food and Drug Administration and Control (NAFDAC) has discovered through routine surveillance and consultations with Master bakers, that the banned lethal chemical "**Potassium Bromate**" that causes cancer is still being used by bakers to enhance bread and other bakeries.

The Agency hereby alerts the general public that FAO/WHO Expert Committee on Food Additives banned the use of **Potassium Bromate** as food additive both in flour milling and baking industry worldwide in 1992. This is as a result of the discovery that it causes cancer, renal failure, and hearing loss. **Potassium Bromate** also reduces nutritional value of bakeries by decomposing vitamins A, B₁, B₂, and E, the main vitamins available in bread and other bakeries.

NAFDAC once more appeals to all bakers to immediately discontinue the use of this life-threatening chemical in their bakeries.

We crave the indulgence of all Nigerians, especially bakery workers, to report the use of **Potassium Bromate** as a bread enhancer, to the nearest NAFDAC office. Your confidentiality will be protected.

ANY BAKERY CAUGHT USING POTASSIUM BROMATE WILL BE CLOSED DOWN INDEFINITELY.

NAFDAC: Safeguarding the health of the Nation

SIGNED: MANAGEMENT

APPENDIX 12 – Letters to State Governors Requesting them to Avail NAFDAC of 30 minutes' Airtime on Radio and Television

NATIONAL AGENCY FOR FOOD AND DRUG ADMINISTRATION AND CONTROL



CORPORATE HEADQUARTERS:

Plot 1057, Ikeja Crescent
Off Oyo Street, Area II,
Section I, Garki Abuja.
Tel: 09 - 2346380 - 3
Fax: 09 - 2346382.

Telegrams: NAFDAC

Your Ref.....

Date.....20.....

Our Ref.....

NAFDAC/DG/2/620/I

8th July, 2002

His Excellency
Chief James Ibori
Governor of Delta State
Government House
Asaba, Delta State

Your Excellency,

REQUEST FOR ALLOCATION OF 30 MINUTES AIR TIME FOR NAFDAC PUBLIC ENLIGHTENMENT JINGLE AND PROGRAMME IN STATE RADIO AND TELEVISION STATIONS

With full assurance of my highest respect for you and a deep commitment towards securing good health for the people of Delta State, I greet you on behalf of the Council, the staff and Management of NAFDAC.

You may recall that on 31st of May, 2001, barely one and a half months after I assumed office in NAFDAC, the Agency held a consultative meeting with Hon. Commissioners of Health from all 36 states of the federation.

Among the factors identified which exposed the public to the danger of fake and counterfeit drugs and other regulated products were:

- General lack of information on the regulatory activities of NAFDAC.
- Low level of awareness of the dangers of fake products.
- Lack of information to the public on how to protect themselves.
- Lack of information and awareness were also blamed for many people running foul of the regulatory guidelines and decrees.

A key agreement at this meeting was that State Governors should avail NAFDAC of the use of at least, 30-minutes, of air time per week in the various states' radio and television.

This will be part of each State's contribution towards taking the NAFDAC message to the citizens especially to the grassroots.

It may interest your Excellency to know that the massive awareness so far created in addressing the identified lapses has been solely due to the effort of NAFDAC.

Sustaining the tempo of this life saving campaign has meant huge outlay of funds to the Agency. The Agency therefore, prays your Excellency to;

- Allocate at least 30-minutes of Free air time in your States' television service for NAFDAC public enlightenment programme.
- Allocate free newspaper space at least once per week for the Agency's public awareness activity.
- Support NAFDAC's activities in any other way with a view to eradicating fake and counterfeit drugs from Nigeria.

Kindly grant the above request so that the citizens of your state will enjoy the full benefit of NAFDAC's public enlightenment programme.

We hereby include the copies of the NAFDAC television and radio jingles for your necessary directive.

Thank you for your anticipated cooperation.

Sincerely,

Dr. Dora N. Akunyili
Dr (Mrs.) Dora N. Akunyili
Director-general (NAFDAC)

APPENDIX 13 – Release of Regulated Products by Customs Officers without Reference to NAFDAC

NATIONAL AGENCY FOR FOOD AND DRUG ADMINISTRATION AND CONTROL

**CORPORATE HEADQUARTERS:**

Plot 1057, Ikeja Crescent
Off Oyo Street, Area II,
Section I, Garki Abuja.
Tel: 09 - 2346380 - 3
Fax: 09 - 2346382.

Telegrams: NAFDAC

Your Ref.....

Date.....20.....

NAFDAC/DG/2/PM/1067/1/92
Our Ref.....
March 14, 2002

The Comptroller-General of Customs
Nigeria Customs Service
Zone 3 Wuse
Abuja

Dear Sir,

**RELEASE OF REGULATED PRODUCTS BY CUSTOMS OFFICERS WITHOUT REFERENCE
TO NAFDAC.**

You may recall sir, that on my assumption of office as the Director General, I paid a consultative visit to your office and you pledged your support to the Agency's goal to eradicate fake and counterfeit drugs from Nigeria.

The drastic effect of importation of fake and counterfeit products on the health of every Nigerian cannot be over emphasized.

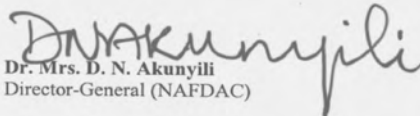
My officers have reported the lack of co-operation by some customs official at the port. (See enclosed 1a). This has necessitated my calling on you once more to call your officers to order so that few bad eggs will not spoil the good image of the Nigerian Customs Services.

We need the maximum co-operation of the customs officials to rid Nigeria of fake and adulterated products.

I count on your timely intervention to safeguard the health of our nation

Thank you.

Yours faithfully,


Dr. Mrs. D. N. Akunyili
Director-General (NAFDAC)

APPENDIX 14 – Continued Release of Fake Pharmaceuticals and other NAFDAC Regulated Products by Resident Customs Officers

**NATIONAL AGENCY FOR FOOD AND DRUG
ADMINISTRATION AND CONTROL**



CORPORATE HEADQUARTERS:
Plot 1057, Ikeja Crescent
Off Oyo Street, Area II,
Section I, Garki Abuja.
Tel: 09 - 2346380 - 3
Fax: 09 - 2346382.

Telegrams: NAFDAC

Your Ref..... Date.....20.....

Our Ref.....
NAFDAC/DG/LA/PORT/INSP/249/VOL.1/162
13th August, 2002.

The Customs Comptroller-General
Nigeria Customs service
Abuja.

Sir,

**CONTINUED RELEASE OF FAKE PHARMACEUTICALS AND OTHER NAFDAC
REGULATED PRODUCTS BY RESIDENT CUSTOMS OFFICERS**

Please the above subject matter refers.

Further to my submission, (see Appendix 1) reference No. NAFDAC/DG/2/CMP/1068/1 of 30th July, 2002 on the above subject matter. I wish to add that some customs officers are not relenting in the release of fake drugs and unwholesome food products.

The cases cited below are the recent releases by the customs officers without reference to NAFDAC.

(1) 1 x 20ft container of Pharmaceuticals imported by Clenton Investment Nigeria Ltd., 73, Adeoye street, opp. Isolo Road, Mushin, lagos.

SGD form No	:	AP/278144
Location	:	Apapa Port.
Agent	:	Ansell Dells & Co 14, Aerodrome Road, Apapa, Lagos.
Custom inspecting officer :		Alozie O. O. Service No. 7771
Custom releasing officer :		Dache B. B. Service No. 34178

(2) 1 x 20ft Container of Pharmaceutical products imported by Krantz Pham and Chemicals Limited, 32, Igbo-Owu Street, Mushin, Lagos.

SGD form No	:	AP/255549
Location	:	Apapa Port.

Agent : Becon and Stat (W.A) AG. LOtd.
Customs inspecting officer : Otu R. O.
Customs releasing officer : Dache B.B. Service No. 34178

- (3) **Importer** : Embassy Pham. & Chem. Ltd.
Product : Skin Ointment
Quantity : 1 x 40ft Container No. CLHU 4154500
SGD No. : AP/2 40586
Agent : Cross Land International Agency Ltd.
- (4) **Importer** : Pescasen Nigeria Ltd.
3rd floor, Tapa House, Lagos.
Product : Orange Necters
Quantity : 1500 cases in 1 x 20ft Container
No. MSKU 225222-3
SGD No. : AP/2 72406
Location : Apapa.
- (5) **Importer** : Relenco International Agency,
Suit 119/120 Hajj Camp
Cargo Terminal
Murtala Muhammed Int. Airport
Ikeja.
Product : 30 cases of Brinedine Tablets (Pharmaceuticals)
Location : NAHCO shed
SGD No : MMC/1 58450
- (6) **Importer** : Hansbro Nigeria Ltd.
239C, Kofo Abayomi Street
Victoria Island-Lagos.
Product : Super Glue
Quantity : 1 x 20ft container No. GSTU 339213-2

(see Appendices 2-7)

Sir your assistance is being solicited to help in curbing this growing trend. If this is allowed to continue, the health of the Nigerian populace will be endangered.

I am counting on your continued co-operation.

Thank you.


Dr. Mrs. D. N. Akunyili
Director-General (NAFDAC)

APPENDIX 15 – Commendation for the Enforcement Squad (Zone A), Lagos

**NATIONAL AGENCY FOR FOOD AND DRUG
ADMINISTRATION AND CONTROL****CORPORATE HEADQUARTERS:**

Plot 1057, Ikeja Crescent
Off Oyo Street, Area II,
Section I, Garki Abuja.
Tel: 09 - 2346380 - 3
Fax: 09 - 2346382.

Telegrams: NAFDAC

Your Ref.....

Date.....20.....

Our Ref.....
LA/PORT/INSP/2/VI/284**March 21, 2002**

The Comptroller-General of Customs
Nigeria Customs Service
Zone 3 Wuse
Abuja

Dear Sir,

COMMENDATION FOR THE ENFORCEMENT SQUAD (ZONE A) LAGOS.

I sincerely wish to express my appreciation for your setting up of the Custom Comptroller General's Special Unit based in Lagos.

The squad has within its short period of existence helped the Agency in apprehending erring importers and clearing agents who evade NAFDAC inspections at the various Ports of Entry.

The officers whose names appear on the list have been of tremendous assistance and deserve your commendation (see the attached).

Finally, I need to commend you for this initiative of setting up the group and appeal for a continued co-operation.

Thank you.

D. N. Akunyili
Dr. Mrs. D. N. Akunyili
Director-General (NAFDAC)

APPENDIX 16 – Final Release of Refined Sugar

**NATIONAL AGENCY FOR FOOD AND DRUG
ADMINISTRATION AND CONTROL****CORPORATE HEADQUARTERS:**

Plot 1057, Ikeja Crescent
Off Oyo Street, Area II,
Section I, Garki Abuja.
Tel: 09 - 2346380 - 3
Fax: 09 - 2346382.

Telegrams: NAFDAC

Your Ref.....

Date.....20.....

Our Ref.....
LA/FORT/INSP/2/VI/284**March 21, 2002**

The Comptroller-General of Customs
Nigeria Customs Service
Zone 3 Wuse
Abuja

Dear Sir,

COMMENDATION FOR THE ENFORCEMENT SQUAD (ZONE A) LAGOS.

I sincerely wish to express my appreciation for your setting up of the Custom Comptroller General's Special Unit based in Lagos.

The squad has within its short period of existence helped the Agency in apprehending erring importers and clearing agents who evade NAFDAC inspections at the various Ports of Entry.

The officers whose names appear on the list have been of tremendous assistance and deserve your commendation (see the attached).

Finally, I need to commend you for this initiative of setting up the group and appeal for a continued co-operation.

Thank you.


Dr. Mrs. D. N. Akunyili
Director-General (NAFDAC)

APPENDIX 17 – The Use of Ethiopian Airlines for the Importation of Counterfeit Medicines



NATIONAL AGENCY FOR FOOD AND DRUG ADMINISTRATION AND CONTROL

CORPORATE HEADQUARTERS, Plot 1052, Ikem Cresent, 401 Oyo Street,
Area 11, Section 1, Garki, Abuja. Tel: 002-2546380-3 Fax: 002-2546382

Director - General

NAFDAC/DG/LLO/435/VOL.1

August 28, 2002

The Managing Director,
Ethiopian Airlines
Addis Ababa
Ethiopia.

Dear Sir/Madam,

THE USE OF ETHIOPIAN AIRLINES FOR THE IMPORTATION OF FAKE DRUGS INTO NIGERIA.

In exercise of the powers conferred on the National Agency for Food and Drug Administration and Control (NAFDAC) by Decree No. 15 of 1993 (as amended), to regulate and control the manufacture, importation, exportation, advertisement, distribution, sale and use of regulated products, namely food, drugs, cosmetics, water, chemicals, medical devices and detergents, the Agency has observed with dismay the flagrant violations of our laws and regulations by the Ethiopian Airlines.

The circulation of fake drugs and other substandard regulated products in Nigeria had been a major source of worry and has embarrassed our health care providers while eroding public confidence on the quality of drugs in circulation.

Hitherto, land and sea borders were major routes of importation. NAFDAC, having considerably intensified surveillance at these borders, the merchants of fake and substandard products have resorted to the use of airlines.

Acting on a tip-off from concerned citizens, NAFDAC inspectors intercepted the following regulated products brought in by various scheduled flights as indicated: 5 drums of Erythromycin powder (ET 951 of 2/8/02), 30 packages of empty Gelatin capsules (ET 921 of 6/8/02), 16 packages of empty Gelatin capsules (ET 951 of 7/8/02), 4 big packages of Tramal capsules (ET 0639 of 22/8/02), Lasix tablets, Neurobion forte injection etc (ET flight of 26/08/02).

It is on record that the flight ET 0639 of 22/8/02 hurriedly took off without offloading all its relevant cargo on sighting NAFDAC officials. Investigation revealed that the said cargo meant for Nigeria was eventually offloaded in Ghana. It stands to reason, that the cargo consisted of fake drugs considering that the few consignments offloaded were all found to be fake.

It is noteworthy to emphasize that the Hon. Minister of Aviation, Dr (Mrs.) Kema Chikwe had warned that any aircraft implicated in the importation of fake drugs into Nigeria will be grounded.

Your airline may have out of ignorance or carelessness allowed this abuse in the past; we therefore request of you as follows:

- A. Ensure that before any drug is accepted to be carried by your aircraft (except drugs meant for personal use), the importer must present NAFDAC registration certificate or authorization letter for the importation of such product (s).
- B. Ensure that the importer has communicated all pre-shipment information to NAFDAC Port Inspection Directorate (PID) before the drug consignment is exported to Nigeria.
 - (i) Name of the drug product(s)
 - (ii) Manufacturer's Name and Address
 - (iii) Quantity being imported
 - (iv) Various pack sizes, strength of the drug and the dosage form.
 - (v) Batch number, manufacture and expiry dates.
 - (vi) Conveying vessel and expected date of arrival.
- C. Drugs from India in addition to A & B above must have certification letter of analysis issued by QCS consultants, (NAFDAC's appointed independent drug analyst in India) which ensures that the products meet stipulated standards.

It is our desired hope that your airline will abide by the rules to rid Nigeria of fake drugs and other substandard products by ensuring that public health rather than commercial interests have primacy in your operational policies.

Your strict compliance with the above is necessary to avoid embarrassment.

Thank you.

Sincerely,


Dr (Mrs.) Dora Akunyili
Director General

APPENDIX 18 – Taste of Soft Drinks from Coca-Cola Nigeria Plc

**NATIONAL AGENCY FOR FOOD AND DRUG
ADMINISTRATION AND CONTROL****CORPORATE HEADQUARTERS:**

Plot 1057, Ikeja Crescent
Off Oyo Street, Area II,
Section I, Garki Abuja.
Tel: 09 - 2346380 - 3
Fax: 09 - 2346382.

Telegrams: NAFDAC

Your Ref.....

Date.....20.....

Our Ref.....

NAFDAC/DG/LLO/431/Vol.1**November 22, 2002**

The Managing Director
Cocacola Nigeria Limited
Pemberton Place
16, Gerrard Road
Ikoyi – Lagos.

Dear Sir,

RE: TASTE OF YOUR SOFT DRINKS PRODUCTSPlease refer to your letter on the above dated 20th August, 2002.

You may wish to know that the greatest number of consumer complaints received by the Agency since its inception has been on your products. Apart from complaint of deleterious products in your drinks, (some of which were brought to the attention of your bottling partner Nigerian Bottling Company) there have also been several complaints about the taste of your drinks in Nigeria which differ from that of some other countries like the United Kingdom, United States and South Africa. In the recent past, the Agency has had to order the destruction of some of your concentrates feared to have expired and some discoloured soft drinks in the premises of your said bottling partner.

As you very well known, part of the statutory functions of the Agency is to determine the stability or otherwise of food for human consumption. Taste of course, is an important aspect of food. The Agency takes all its functions with utmost seriousness particularly such as the above, that deal with food or drugs for human consumption.

In the light of the above, you are requested to submit to the Agency as a matter of urgency the detailed results of taste tests conducted by your company in Nigeria since 1994 inclusive of the modalities for conducting the said tests.

Please treat with utmost dispatch..

Yours faithfully,

DNAKunyili
DR (MRS.) DORA N. AKUNYILI
DIRECTOR GENERAL

APPENDIX 19 – Auctioning of NAFDAC Regulated Products As Overtime Cargo**NATIONAL AGENCY FOR FOOD AND DRUG
ADMINISTRATION AND CONTROL****CORPORATE HEADQUARTERS:**

Plot 1057, Ikeja Crescent
Off Oyo Street, Area II,
Section I, Garki Abuja.
Tel: 09 - 2346380 - 3
Fax: 09 - 2346382.

Telegrams: NAFDAC

Your Ref.....

Date.....20.....

NAFDAC/LA/PORT/INSP/249/VOL.1/190
4th October, 2002

The Controller General
Nigeria Customs Service
Abuja.

Dear Sir,

AUCTIONING OF NAFDAC REGULATED PRODUCTS AS OVERTIME CARGO

Please above subject matter refers.

The National Agency for Food and Drug Administration and Control (NAFDAC) is worried about the number of regulated products auctioned as Overtime Cargo without reference to the Agency.

These auctioned regulated products, which are most often expired/unwholesome, are sold in open market thereby endangering the health of consumers.

Two of such recent auctions are:

- (1) The 1 X 40 container of expired drugs auctioned at Onne ports, Rivers State, but subsequently by the Agency on 20th August, 2002.
- (2) A 1 X 20 container No. MOLU224716-6 of expired wines auctioned at Kirikiri Lighter Terminal Phase 3, Lagos, for which NAFDAC had issued seizure to the Customs and NPA on 17/9/2002.

To avert similar reoccurrence, it is hereby suggested that:

- a. NAFDAC officers in any port with goods to be auctioned be included in the Customs Committee on Abandoned Goods and overtime Cargo.
- b. That such auctioned regulated goods be released through the existing channels for the release of regulated products.

These would ensure that only safe and wholesome regulated products are sold to the consumers.

Thank you.


Dr. (Mrs.) D. N. Akunyili
Director General (NAFDAC)

APPENDIX 20 – Re-Auctioning of NAFDAC Regulated Products by Nigeria Custom Service as Overtime Cargo

NATIONAL AGENCY FOR FOOD AND DRUG ADMINISTRATION AND CONTROL



NAFDAC CORPORATE HQ:
Plot 2032 Olusegun Obasanjo Way,
Zone 7, Wuse - Abuja.
Tel: +234-9-5240994
Tel/Fax: +234-9-5241461
E-mail: nafdac@nafdac.gov.ng
Website: www.nafdac.gov.ng

LAGOS LIAISON OFFICE:
Central Laboratory
No 5, Oshodi Apapa Expressway,
Near Oshodi Flyover, Lagos
Tel: +234-1-4731018
Tel: +234-1-4524259
Tel: +234-1-4521212
Tel/Fax: +234-1-4528031

Director-General

NAFDAC/DG/2/CC/1067
August 7, 2003

The Controller General
Nigeria Custom Service
Abuja.

Dear Sir,

RE-AUCTIONING OF NAFDAC REGULATED PRODUCTS BY NIGERIA CUSTOM SERVICE AS OVERTIME CARGO.

I wish to humbly refer the Controller General to my letter on the above subject Reference LA/PORT/INSP/249/VOL.1/190 of 4th October 2002 (see attached for ease of reference), and to inform you that your officers have continued to auction NAFDAC regulated products such as drugs, food, cosmetics, medical devices, bottled water and chemicals as overtime cargo without reference to the Agency.

We expressed our concern over this when two containers of expired drugs and wines were auctioned to the public in August and September last year. The situation hasn't changed inspite of this letter.

On the 18th of July 2003, another set of overtime cargo was being examined for auctioning at the Lilypond Terminal Ijora. Among these overtime cargo are two (2) 20ft containers which contains the following:

- (a) **Felvacarp** (Piroxicam capsules U.S.P), an unregistered product suspected to be fake and infested with moulds.
- (b) **Paracinol** (Acetaminophen capsules U.S.P), an unregistered product suspected to be fake (Find attached samples).

Sir, we have repeatedly requested to be appointed into the custom Committee on Abandoned Goods and Overtime Cargo, so that NAFDAC regulated products could be released through appropriate existing channels to avert recycling of fake and unregistered regulated products. This has not happened. We would like to appeal once more for our inclusion into this committee and that our officers be invited before any NAFDAC regulated products are presented for auction, including the above stated items.

Please accept the assurances of my highest esteem and best regards.

Sincerely,

Dr. Dora N. Akunyili
Dr. Dora N. Akunyili (OFF)
Director General

APPENDIX 21a – NAFDAC SOP for Pre-Registration Inspection of Drug Manufacturing

 National Agency for Food and Drug Administration and Control (NAFDAC)		STANDARD OPERATION PROCEDURE <i>(Confidential document please do not photocopy)</i> SOP TITLE: Pre-Registration Inspection of Drug Manufacturing Establishment	
<i>Prepared by/date</i>	<i>Approved by/Date (DD/Food EID HQ)</i>	<i>Originating Directorate:</i>	
		<i>Doc Ref. No. : EID-002-00</i>	
<i>Approved by/date: D/EID</i>		<i>Effective Date:</i>	
		<i>Review Due Date:</i>	
		<i>Page:</i>	

PURPOSE

To describe the procedure to be followed for inspection of drug manufacturing establishment to ascertain that the factory is suitable for production of pharmaceuticals for which the client is applying.

SCOPE

This document covers all intended NAFDAC regulatory inspection of any drug manufacturing establishment in Nigeria for the purpose of product registration.

RESPONSIBILITY

The selected Regulatory officers involve in the inspection assignment are responsible for the implementation of this procedure.

The DD-Drug EID and respective unit heads are responsible for adherence to the provision of this SOP.

 National Agency for Food and Drug Administration and Control (NAFDAC)		STANDARD OPERATION PROCEDURE <i>(Confidential document please do not photocopy)</i> SOP TITLE: Pre-Registration Inspection of Drug Manufacturing Establishment	
Prepared by/date		Approved by/Date (DD/Food EID HQ)	
		Originating Directorate:	
		Doc Ref. No.: EID-002-00	
Approved by/date: D/EID		Effective Date:	
		Review Due Date:	
		Page:	

PROCEDURE

1. DEFINITIONS / ABBREVIATIONS

- Client – Corporately registered company that intend to manufacture a regulated product
- SOP- standard operation procedure
- Regulatory officer- NAFDAC staff responsible for inspection of premises of manufacturer of regulated products.
- Regulated product- food, drug, package water, medical devices, vaccine /biological etc.
- Inspection Team- The selected regulatory officers responsible for carrying out a particular facility inspection.

 National Agency for Food and Drug Administration and Control (NAFDAC)		STANDARD OPERATION PROCEDURE (Confidential document please do not photocopy) SOP TITLE: Pre-Registration Inspection of Drug Manufacturing Establishment	
<i>Prepared by/date</i>	<i>Approved by/Date (DD/Food EID HQ)</i>	Originating Directorate: Doc Ref. No : EID-002-00	
<i>Approved by/date: D/EID</i>		Effective Date:	
		Review Due Date:	
		Page	

2. PROCEDURE

1. Preparation for the inspection should be organised and implemented according to SOP number EID-018-00
2. Pre-Inspection meeting is conducted at the premises of the client according to the following steps:
 - a. The team members are welcomed to the company by the leader of the client's team who should also do the introduction of members of his/her team.
 - b. The leader of the NAFDAC team explains the team's mission and introduces the other members of the team.
 - c. Agenda and timing for the inspection is agreed i.e. documents revision and format for facility tour.
3. The Inspection is conducted using the standard checklist as contained in Annexure I.
4. Each Inspector MUST fill the checklist individually with observed comments, and the completed/signed document should be submitted to the team leader to be filed as part of the inspection record after the exercise.
5. The product is sampled for NAFDAC laboratory analysis by the regulatory officers following the SOP on *sampling during Inspection for processed food/packaged water* SOP number EID-019-00
6. A brief meeting of the NAFDAC team should be held to combine and summarise all the observations/lapses for presentation by the team leader.

 National Agency for Food and Drug Administration and Control (NAFDAC)		STANDARD OPERATION PROCEDURE <i>(Confidential document please do not photocopy)</i> SOP TITLE: Pre-Registration Inspection of Drug Manufacturing Establishment	
Prepared by/date:	Approved by/Date (DB/Food EID HQ)	Originating Directorate:	
		Doc Ref. No. : EID-002-00	
Approved by/date: D/EID		Effective Date:	
		Review Due Date:	
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7. Following the NAFDAC brief meeting, post-inspection meeting should be held by the client/NAFDAC teams where inspection findings/observations should be discussed. Attendance record of this meeting should be obtained and kept as part of the inspection record.
8. Any lapses observed should be communicated to the client through issuance of compliance directives according to the procedure stated in SOP number EID-011-00.
9. Final report of the inspection should be prepared using the collated checklist by the team according to SOP number EID-012-00

CHANGE HISTORY & RATIONALE		
Date	SOP Ref No	Reason For Review
		New SOP

TRAINING REQUIREMENTS
EID
EID Regulatory Officers

 National Agency for Food and Drug Administration and Control (NAFDAC)		STANDARD OPERATION PROCEDURE (Confidential document please do not photocopy) SOP TITLE: Pre-Registration Inspection of Drug Manufacturing Establishment	
Prepared by/date	Approved by/Date (DD/Food EID HQ)	Originating Directorate:	
		Doc Ref. No.: EID-002-00	
Approved by/date: D/EID		Effective Date:	
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APPENDIX 21b–NAFDAC SOP for Anti-Counterfeiting Activities and Blacklisting Of Erring Companies

 National Agency for Food and Drug Administration and Control (NAFDAC)	STANDARD OPERATION PROCEDURE TITLE: ANTICOUNTERFEITING ACTIVITIES & BLACKLISTING OF ERRING COMPANIES		
	Originating Directorate: PHARMACOVIGILANCE (PVG/FDIC)		
<i>Prepared by/date (DD/PVG-FDIC) 3rd November, 2008</i>	<i>Approved by/Date Anti-counterfeiting Committee</i>	Doc Ref. No.: PVG-003-00	Effective Date:
<i>Approved by/date (Director General-NAFDAC)</i>		Review Due Date:	Page

PURPOSE

To describe the activities involved in responding to alerts on counterfeiting and outlines the procedure to be followed in blacklisting erring companies.

SCOPE

This procedure covers the stepwise approach in handling alerts relating to counterfeiting of regulated products, document forgery, fraudulent practices, as well as unauthorized access to NAFDAC registration database and applies to all Directorates in NAFDAC.

 National Agency for Food and Drug Administration and Control (NAFDAC)	STANDARD OPERATION PROCEDURE TITLE: ANTICOUNTERFEITING ACTIVITIES & BLACKLISTING OF ERRING COMPANIES	
	Originating Directorate: PHARMACOVIGILANCE (PVG/FDIC)	
<i>Prepared by/date (DD/PVG-FDIC) 3rd November, 2008</i>	<i>Approved by/Date Anti-counterfeiting Committee</i>	Doc Ref. No.: PVG-003-00 Effective Date:
<i>Approved by/date (Director General-NAFDAC)</i>		Review Due Date: Page

RESPONSIBILITY

The assigned PVG/FDIC officer shall commit to the implementation of the SOP in accordance with the procedures listed.

The DD- PVG/FDIC shall ensure compliance with the procedures listed in this SOP.

Anti-counterfeiting committee is responsible for reviewing report of appropriate Directorate(s) and submission from offenders. The committee is also responsible for advising the Director General on next line of action.

PROCEDURE

1. DEFINITIONS / ABBREVIATIONS

- a. PVG - Pharmacovigilance
- b. FDIC - Food and Drug Information Centre
- c. ENF- Enforcement
- d. NCS - Narcotics and Control Substances

 National Agency for Food and Drug Administration and Control (NAFDAC)	STANDARD OPERATION PROCEDURE TITLE: ANTICOUNTERFEITING ACTIVITIES & BLACKLISTING OF ERRING COMPANIES	
	Originating Directorate: PHARMACOVIGILANCE (PVG/FDIC)	
<i>Prepared by/date (DD/PVG-FDIC) 3rd November, 2008</i>	<i>Approved by/Date Anti-counterfeiting Committee</i>	Doc. Ref. No.: PVG-003-00
<i>Approved by/date (Director General-NAFDAC)</i>		Effective Date:
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- e. R&R – Registration and Regulatory Affairs
- f. PID – Ports Inspection Directorate
- g. EID – Establishment Inspectorate Directorate
- h. SA – Special Assistant
- i. SOP – Standard Operation Procedure
- j. Fraudulent Practices
 - Use of fake manufacturing address
 - Use of fake name to manufacture/import
 - Use of genuine/registered importer without his authorization
 - Such other offences as may be legally deemed fraudulent

 National Agency for Food and Drug Administration and Control (NAFDAC)	STANDARD OPERATION PROCEDURE <i>TITLE: ANTICOUNTERFEITING ACTIVITIES & BLACKLISTING OF ERRING COMPANIES</i>	
	Originating Directorate: PHARMACOVIGILANCE (PVG/FDIC)	
<i>Prepared by/date (DD/PV/G-FDIC): 3rd November, 2008</i>	<i>Approved by/Date Anticounterfeiting Committee</i>	Doc Ref. No.: PVG-003-00
<i>Approved by/date (Director General - NAFDAC)</i>		Effective Date:
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1. PROCEDURE:

- a. Information on (suspected violation by companies, suspected imitation/counterfeiting of regulated products, circulation of counterfeit, substandard & unwholesome products, document forgery, fraudulent practices, unauthorized access to NAFDAC registration database) is received from both internal and external sources which includes; Director General NAFDAC, NAFDAC Directors, Local, Regional & International regulatory agencies, Internet sources, foreign analysts, National security Agencies, owners of products, routine surveillance/investigative reports, general public, media etc.
- b. Received information is forwarded/communicated to the DD (PVG/FDIC) who directs internal (PVG/FDIC) preliminary investigation. (*The processing involves information verification and communication with relevant Directorate(s).*) (See relevant directorates on annexure 1 attached.)
- c. Findings by relevant Directorate(s) to be forwarded to the DD PVG/FDIC for collation and notification of Anti-counterfeiting committee members.

 National Agency for Food and Drug Administration and Control (NAFDAC)	STANDARD OPERATION PROCEDURE TITLE: ANTICOUNTERFEITING ACTIVITIES & BLACKLISTING OF ERRING COMPANIES	
	Originating Directorate: PHARMACOVIGILANCE (PVG/FDIC)	
<i>Prepared by/date (DD/PVG-FDIC) 3rd November, 2008</i>	<i>Approved by/Date Anti-counterfeiting Committee</i>	Doc Ref. No.: PVG-003-00
		Effective Date:
<i>Approved by/date (Director General-NAFDAC)</i>	Review Due Date:	
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- d. An invitation letter to be sent to the indicted company(ies) for submission of explanation/defense if deemed necessary.
- e. Depending on the seriousness and sensitivity of the findings, a committee meeting would be convened for review. (See annexure 2 for list of committee members.)
- f. The committees' recommendation on the action(s) to be taken would be communicated to the Director General NAFDAC for approval.
- g. The company would be informed on the final line of action to be taken by the Agency and a public alert to be issued using the most appropriate media.
- h. All documents and correspondences relating to the Alert Notification to be filed appropriately as security document.

 National Agency for Food and Drug Administration and Control (NAFDAC)	STANDARD OPERATION PROCEDURE <i>TITLE: ANTICOUNTERFEITING ACTIVITIES & BLACKLISTING OF ERRING COMPANIES</i>		
<i>Prepared by/date</i> <i>November, 2008</i> <i>(DD/PVG-FDIC)</i>	<i>3rd</i> <i>Approved by/Date Anti-counterfeiting Committee</i>	<i>Doc Ref No.: PVG-003-00</i>	<i>Effective Date:</i>
<i>Approved by/date</i> <i>(DG-NAFDAC)</i>		<i>Review Due Date:</i>	<i>Page</i>

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28-10-2008		New SOP

ANNEXURE 1**LIST OF DIRECTORATES**

1. Establishment Inspection Directorate
2. Ports Inspection Directorate
3. Narcotics Control Substances Directorate
4. Enforcement Directorate
5. Registration and Regulatory Affairs Directorate

ANNEXURE 2**LIST OF COMMITTEE MEMBERS**

- Director EID
- Director PID
- Director NCS
- Director R&R
- Director Enforcement
- Deputy Director Legal
- Deputy Director PVG/FDIC
- Deputy Director SA Lagos

APPENDIX 21c– NAFDAC SOP for Release of Parallel Importation of Food Products

 National Agency for Food and Drug Administration and Control (NAFDAC)	STANDARD OPERATION PROCEDURE <i>TITLE: RELEASE OF PARALLEL IMPORTATION OF FOOD PRODUCTS.</i>	
	Originating Directorate: ENFORCEMENT DIRECTORATE	
<i>Prepared by/date (D-ENFORCEMENT)</i>	<i>Approved by/Date Enforcement Directorate</i>	Doc Ref. No.:
		Effective Date:
<i>Approved by/date (DG-NAFDAC)</i>		Review Due Date:
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PURPOSE

To describe the procedure for the release of parallel importation of food products.

SCOPE

This procedure covers the stepwise approach in accessing and releasing parallel imported food products.

RESPONSIBILITY

The assigned PID officers at the port of entry shall commit to the implementation of this SOP in accordance with the procedures listed.

The D (PID) shall ensure compliance with the procedures listed in this SOP.

 National Agency for Food and Drug Administration and Control (NAFDAC)	STANDARD OPERATION PROCEDURE <i>TITLE: RELEASE OF PARALLEL IMPORTATION OF FOOD PRODUCTS.</i>	
	Originating Directorate: ENFORCEMENT DIRECTORATE	
<i>Prepared by/date (D- ENFORCEMENT)</i>	<i>Approved by/Date Enforcement Directorate</i>	Doc Ref. No.:
<i>Approved by/date (DG-NAFDAC)</i>	Effective Date:	Review Due Date:
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PROCEDURE

The product will be sampled for analysis

The imported products will be placed on HOLD

The importer will pay the prescribed fee for analysis.

If product fails analysis, importer will forfeit the product, pay the cost for the destruction and will be prosecuted by NAFDAC.

If product passes analysis, a first offender will pay a fine of 5 million naira for a 40 ft container, 3 million naira for a 20 ft container or 2 million naira for half a container or less to NAFDAC.

 National Agency for Food and Drug Administration and Control (NAFDAC)	STANDARD OPERATION PROCEDURE <i>TITLE: RELEASE OF PARALLEL IMPORTATION OF FOOD PRODUCTS.</i>	
	Originating Directorate: ENFORCEMENT DIRECTORATE	
<i>Prepared by/date (D- ENFORCEMENT)</i>	<i>Approved by/Date Enforcement Directorate</i>	Doc Ref. No.:
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Payment must be in bank draft payable to National Agency for Food and Drug Administration and Control.

The importer will write a letter of undertaking never to import registered brands of another owner again, and will be ready to face prosecution if he does.

NAFDAC will issue a letter of warning to the importer never to engage in such practices again.

Products will be released to importer after satisfying these requirements.

If importer does not satisfy the requirements, products will be seized and transferred to customs for auction.

For a second offender, there will not be any option of fine. Products will be forfeited and importer will be prosecuted by NAFDAC.

APPENDIX 21d–NAFDAC SOP for Inspection of Containerised Chemicals
(Finished Chemicals, Controlled Chemicals and Narcotics)

 National Agency for Food and Drug Administration and Control (NAFDAC)	STANDARD OPERATION PROCEDURE <i>TITLE: INSPECTION OF CONTAINERISED CHEMICALS (FINISHED CHEMICALS, CONTROLLED CHEMICALS AND NARCOTICS).</i>	
	Originating Directorate: PORTS INSPECTION DIRECTORATE	
<i>Prepared by/date (PID)</i>	<i>Approved by/Date</i>	Doc Ref. No.:
<i>Approved by/date (DG-NAFDAC)</i>		Effective Date:
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PURPOSE

To describe the process involved in the inspection of Chemicals in order to ensure that only right and quality chemicals are imported into the country.

SCOPE

The process outlined in this document shall apply to all chemicals imported through the various Ports of entry/ Land Borders.

RESPONSIBILITY

- Regulatory Officer shall be committed to the implementation of the activities in the procedure
- PORT HEAD shall supervise all the activities involved in this SOP
- Director shall be responsible for the overall compliance

 National Agency for Food and Drug Administration and Control (NAFDAC)	STANDARD OPERATION PROCEDURE <i>TITLE: INSPECTION OF CONTAINERISED CHEMICALS (FINISHED CHEMICALS, CONTROLLED CHEMICALS AND NARCOTICS).</i>	
<i>Prepared by/date (PID)</i>	<i>Approved by/Date</i>	Doc Ref. No.:
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PROCEDURE

DEFINITIONS / ABBREVIATION

- PH = Port Head
- RO = Regulatory Officer/Laboratory Technologist
- RAR = Risk assessment report
- C of A = Certificate of analysis

 National Agency for Food and Drug Administration and Control (NAFDAC)	STANDARD OPERATION PROCEDURE <i>TITLE: INSPECTION OF CONTAINERISED CHEMICALS (FINISHED CHEMICALS, CONTROLLED CHEMICALS AND NARCOTICS).</i>	
	Originating Directorate: PORTS INSPECTION DIRECTORATE	
<i>Prepared by/date (PID)</i>	<i>Approved by/Date</i>	Doc Ref. No.:
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PROCEDURE

I. The RO should receive the following from the Clearing Agent:

- Bill of Lading,
- Current Chemical Import Permit
- Permit to Import & Clear (in the case of Controlled Chemicals)
- RAR
- Packing list
- C of A

NAFDAC Receipt of payment

 National Agency for Food and Drug Administration and Control (NAFDAC)	STANDARD OPERATION PROCEDURE <i>TITLE: INSPECTION OF CONTAINERISED CHEMICALS (FINISHED CHEMICALS, CONTROLLED CHEMICALS AND NARCOTICS).</i>	
	Originating Directorate: PORTS INSPECTION DIRECTORATE	
<i>Prepared by/date (PID)</i>	<i>Approved by/Date</i>	Doc Ref. No.:
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1. The RO should proceed to the examination bay where the container is positioned to carry out inspection within 1 hour upon receipt of the document.
2. The RO should check the integrity of the Seal of the container.
3. The RO should undertake the physical inspection of the container and note the following information on the product;
 - the Batch No.,
 - Production & Expiry dates,
 - Country of Origin,
 - Manufacturer's name & address,
 - Chemical Hazard Symbol,
 - Type of container.

 National Agency for Food and Drug Administration and Control (NAFDAC)	STANDARD OPERATION PROCEDURE <i>TITLE: INSPECTION OF CONTAINERISED CHEMICALS (FINISHED CHEMICALS, CONTROLLED CHEMICALS AND NARCOTICS).</i>	
	Originating Directorate: PORTS INSPECTION DIRECTORATE	
<i>Prepared by/date (PID)</i>	<i>Approved by/Date</i>	Doc Ref. No. .
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1. The RO should record all information so far gathered into his / her note book.
2. The RO should fill the physical inspection form using the information obtained from the product on inspection.
3. If all above information are satisfactory, the RO should recommend for release to the PH.
4. If information is not satisfactory, the RO should note the default on the inspection form and communicate to PH by phone for necessary action.
5. The RO should give the physical inspection form to the Agent for onward transmission to the PH.
6. If information is satisfactory, the PH should release the consignment
7. If information is unsatisfactory, the PH should give conditional release, then refer to the SH, Ports Chemicals or Ports Drugs (Controlled substances/ Narcotics)
8. If chemical has expired, the PH should refer to Sectional Head, for next line of action

 National Agency for Food and Drug Administration and Control (NAFDAC)	STANDARD OPERATION PROCEDURE <i>TITLE: INSPECTION OF CONTAINERISED CHEMICALS (FINISHED CHEMICALS, CONTROLLED CHEMICALS AND NARCOTICS).</i>	
	Originating Directorate: PORTS INSPECTION DIRECTORATE	
<i>Prepared by/date (PID)</i>	<i>Approved by/Date</i>	Doc Ref. No.:
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 National Agency for Food and Drug Administration and Control (NAFDAC)	STANDARD OPERATION PROCEDURE <i>TITLE: INSPECTION OF CONTAINERISED CHEMICALS (FINISHED CHEMICALS, CONTROLLED CHEMICALS AND NARCOTICS).</i>	
	Originating Directorate: PORTS INSPECTION DIRECTORATE	
<i>Prepared by/date (PID):</i>	<i>Approved by/Date:</i>	Doc Ref. Nos:
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TRAINING REQUIREMENTS

PID			
Director	Sectional Heads	Port Heads	Regulatory officers

	National Agency for Food & Drugs Administration and Control, Oshodi. Pesticide Residue Analysis Laboratory.
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S/No	Functions	Name	Start of duty	End of duty	Signature
	Responsible officer	Working Analyst	13-05-2004		
	Back-up	Laboratory Assistant			



**National Agency for Food & Drugs Administration and
Control, Oshodi.**

Pesticide Residue Analysis Laboratory.

1.0 TITLE: EXTRACTION METHOD FOR TOMATO USING ETHYL ACETATE

2.0 PURPOSE: To determine the pesticide residue in tomato samples

3.0 SCOPE: This SOP shall be followed by all analysts conducting analysis on tomato samples.

4.0 REAGENTS

4.1 Ethyl acetate, pesticide residue grade

4.2 Cyclohexane, PR grade

4.3 Sodium hydrogen carbonate, analar grade

4.4 Sodium sulphate, anhydrous

5.0 APPARATUS

5.1 Ultra Turax

5.2 Calibrated tubes

5.3 Rotary evaporator

6. 0 PROCEDURE

6.1 Take 30g sample

6.2 Add 60ml ethyl acetate.

6.3 Add 5g sodium hydrogen carbonate.

6.4 Blend with Ultra Turrax for 2 mins.



**National Agency for Food & Drugs Administration and Control,
Oshodi.**

Pesticide Residue Analysis Laboratory.

- 6.5** Add 35g anhydrous sodium sulphate. Transfer 10ml into a rotary flask to give a concentration of 0.5g/ml.
- 6.6** Concentrate the 10ml solution to near dryness, by rotary evaporator to about 1ml and to near dryness by nitrogen gas.
- 6.7** Add 1 ml of ethyl acetate/cyclohexane 1:1.
- 6.8** Transfer to a calibrated tube rinsing the flask with 2mL ethyl acetate/cyclohexane 1:1.
- 6.9** Evaporate to 1 mL under nitrogen gas.

7.0 GPC CLEAN UP

Refer to PRL/SOP/01 for GPC or PRL/SOP/02 for Alumina clean up

- 7.1** Inject 500ul to GPC for clean up.
- 7.2** Discard the first 8ml and collect the next 9 to 20ml.
- 7.3** Evaporate to near dryness in a rotary evaporator and complete the drying with nitrogen gas.
- 7.4** Make up with n-Hexane to 1 ml in a calibrated tube to give a concentration of 2.5g/ml. This is ready for GC/NPD and GC/FPD analysis.
- 7.5** For GC/ECD analysis, take 40ul from the 1 ml and make up to 1 ml with hexane in a calibrated tube to give a concentration of 0.1 g sample/ml.



**National Agency for Food & Drugs Administration and Control,
Oshodi.**

Pesticide Residue Analysis Laboratory.

8.0 GAS CHROMATOGRAPHIC ANALYSIS

Refer to **PRL/ SOP/09.step 07**

APPENDIX 22 – Violation of Labelling Requirements for Alcoholic Beverages

**NATIONAL AGENCY FOR FOOD AND DRUG
ADMINISTRATION AND CONTROL****CORPORATE HEADQUARTERS:**

Plot 1057, Ikeja Crescent
Off Oyo Street, Area II,
Section I, Garki Abuja.
Tel: 09 - 2346380 - 3
Fax: 09 - 2346382.

Telegrams: NAFDAC

Your Ref.....

Date.....20.....

Our Ref.....

NAFDAC/SD/BREWERS/02/1**June 11, 2002**

The Chief Executive Officer
Golden Guinea Breweries PLC
Aba Road, Umuahia
Abia State.

Dear Sir,

VIOLATION OF LABELLING REQUIREMENTS FOR ALCOHOLIC BEVERAGES

NAFDAC has observed that many Brewers and Importers of beer are violating the labeling requirement for this regulated product. In the labeling of alcoholic beverages, such as beer, it is mandatory that **percentage alcohol content** is clearly stated. It is also mandatory that the **"BEST BEFORE DATE"** is clearly stated.

You are hereby notified that with effect from 1st December 2002, any beer produced, imported or offered for sale in Nigeria without the **"BEST BEFORE DATE"** and the **percentage alcohol content clearly stated shall be impounded and destroyed by NAFDAC.**

Thank you.

Pharm. (Mrs.) Adeline I. Osakwe
For: DIRECTOR GENERAL(NAFDAC)

APPENDIX 23 – Public Notice to Beer Brewers and Dealers

**NATIONAL AGENCY FOR FOOD AND DRUG
ADMINISTRATION AND CONTROL (NAFDAC)****CORPORATE HEADQUARTERS**

Plot 1057, Ikeja Crescent, off Oyo Street Area 11 Section 1,
Garki, Abuja. Tel: 09-234680 – 3 Fax: 09 – 2346382

NOTICE TO BEER BREWERS/DEALERS

NAFDAC has observed that many brewers and importers of beer are violating the labeling requirements for this regulated product. In the labeling of Alcoholic Beverages, such as Beer, it is mandatory that “**PERCENTAGE ALCOHOL CONTENT**” and the “**BEST BEFORE DATE**” is clearly declared on the label.

NAFDAC hereby notifies all Beer Brewers and dealers that, with effect from **1st DECEMBER 2002**, any beer produced, imported or offered for sale in Nigeria without the “**BEST BEFORE DATE**” and the “**PERCENTAGE ALCOHOL CONTENT**” clearly stated on the label, shall be impounded and destroyed by NAFDAC.

Signed
MANAGEMENT

NAFDAC: Safeguarding the health of the Nation.

APPENDIX 24 – Comprehensive List of Awards, Scholarships and Recognitions

I have received over 500 **Awards and Recognitions** locally and internationally. In order not to make this book too bulky, I am listing some of the Awards and Recognitions as shown in the table that follows:

	AWARD	AWARDING BODY	DATE
1	Food Fortification Initiative Award	Food Fortification Initiative, Arusha, Tanzania.	17-11-2008
2	Distinguished Professionalism Award	University of Nigeria Alumni Association, Awka Branch	6-09-2008
3	Award of Excellency	National Association of Anambra State Students (NAASS), OAU Chapter.	Sept 2008
4	Good Governance and Visionary Leadership Award	Crusade for Greater Nigeria on Eradication & Social Matters (CFGN)	21-8-2008
5	Great Achiever Award	Igbo Women Progressive Forum, Northern States Chapter (Nwanyi Bu Ulo)	29-7-2008
6	Honorary Award	Government of Ekiti State	28-7-2008
7	Fellowship Award	Centre for Research and Information on Substance Abuse (CRISA)	23-07-2008
8	Gold Service Award On Vocational Services	Rotary International District 9140	19-7-2008
9	Prix Galien Afrique Award	Gabonese Pharmaceutical Forum	6-6-2008
10	Youth Personality and Role Model Award	2008 University of Nigeria Enugu Campus Graduating Students	30-5-2008
11	Award of Fellowship	Chartered Institute of Arbitrators Nigeria	2-5-2008
12	Merit Award	Africa International Media Organisation	1-5-2008
13	Achievement of Excellence Award	Maranatha Household World Ministries	April, 2008
14	Most Outstanding Administrator	Grassroots Media Ventures Ltd	April, 2008
15	Honorary Award	Ladoke Akintola University of Technology	21-4-2008
16	Role Model Award (PROMA 2008)	Association of Professional Women on Rural Development	10-4-2008
17	Inspirational Leadership Award	The Joint Northern Youth Association	5-4-2008
18	Award of Excellence	The Graduate Students' Association, Uniport in Collaboration with the Caritas Empowerment & Development Initiative	April 2008
19	A True Nigerian Icon Award	The News Magazine.	March 2008
20	BIOSSA Personality of The Year 2007 Award	Babcock University	March 2008

	AWARD	AWARDING BODY	DATE
21	Outstanding Leaders Gold Award	News in Africa	19-3-2008
22	Prize for Courage	Church of God Mission International Inc.	16-3-2008
23	Fellow of Good Governance	Institute of Governance & Management Nigeria (IGM)	15-3-2008
24	2008 African Heroine	Ohio University African Students' Union, Ohio, USA	Feb 23, 2008
25	Merit Award	The Quest Organisation	23-2-2008
26	Award of Excellency	Youth Movement of Ebonyi State, Nigeria	21-2-2008
27	Distinguished Anti-Fake Drug Crusader of the Year 2007	National Daily Newspaper	31-1-2008
28	Award of Excellence	Nigerian Institute of Management/ National Youth Service Corps Initiative	Jan. 2008
29	Integrity Award	Code of Conduct Bureau, Nigeria	12-12-2007
30	Honorary Fellow of the Institute	Chartered Institute of Purchasing & Supply Management of Nigeria	12-12-2007
31	International Public Servant of the Year Award	Executive Reach	06-12-2007
32	Fortification Award	CANET	06-12-2007
33	Best African Leader and Diaspora Affairs Award 2007	African Youth Foundation	06-12-2007
34	International Woman of the Year Award	Regional Council of Aosta Valley, Italy in Collaboration with International Soroptimist Club and Autonomous Region of Aosta	30-11-2007
35	Distinguished Merit Award	Supreme Niger Delta Youth Council Worldwide	26-11-2007
36	Award of Excellence	Catholic Chaplaincy of the Nigeria Police Force	15-11-2007
37	Distinguished Alumni Award	University of Nigeria Alumni Association, Kwara State Branch	Nov. 2007
38	Meritorious Service Award	Anambra State Towns (People) Association, Abuja	Nov. 2007
39	Honorary Award	Ministry of Women Affairs and Social Development, Awka, Anambra State, Nigeria	Nov. 2007
40	International Service Award	Rotary International District 9140, Enugu State, Nigeria	Nov. 2007
41	Distinguished Person Media Award	African American Pride Media Group	Nov. 2007

	AWARD	AWARDING BODY	DATE
42	Excellent Merit Award	Special Persons Association Of Nigeria (S.P.A.N)	24-10-2007
43	UNN-USA Alumni & Friends Lifetime Achievement Award	University of Nigeria Nsukka Alumni And Friends Association, USA	20-10-2007
44	Award of Excellence in Service	Umuma Ebenmano Development & Cultural Union (Women's Wing, Lagos Branch)	20-10-2007
45	Woman of Substance Award	Association of Table Water Producers, Oyo State Chapter, Ibadan	17-10-2007
46	Honorary Award	Government of Oyo State, Nigeria	17-10-2007
47	Honorary Merit Award	Stem Cell Transplantation Project for Africa	Oct. 2007
48	Merit Award	National Association of Biochemistry Students (NABS), University of Jos Chapter, Plateau State	15-09-2007
49	Outstanding Leadership Award	Nigerian Association of Pharmacists & Pharmaceutical Scientists in the Americas (NAPPSA)	14-09-2007
50	Honorary Fellowship Award	Nigerian Psychological Association (NPA), Abuja	13-09-2007
51	Honorary Award	Nigerian Medical Association	18-08-2007
52	The Pride of Womanhood	Women Advancement for Economic & Leadership Empowerment in Africa	Aug. 2007
53	Award of Excellence	Student Union Government (SUG), Federal Polytechnic, Nassarawa	11-08-2007
54	Honorary Award	University of Nigeria Alumni Association, Lagos Branch	10-08-2007
55	Honorary Award	The City People Media Group	14-07-2007
56	Fresh Walls Award	Fresh Walls Foundation, Enugu	07-07-2007
57	Distinguished Award of Honour and Excellence	Church of Nigeria Anglican Communion, Diocese of Enugu	01-07-2007
58	Placement in the Roll of Honour	Nigerian Association of Hospital & Administrative Pharmacists (NAHAP), Ondo State Branch	27-06-2007
59	Global Anti-Counterfeiting Awards 2007	Global Anti-Counterfeiting Group	26-06-2007
60	Award as Frontier of Good Legacy in Nigeria	Students' Union Government, Federal Polytechnic, Bida, Niger State, Nigeria	June 2007

	AWARD	AWARDING BODY	DATE
61	Exceptional Merit Award for Exceptional Women Educationalists	Forum for African Women Educationalists (FAWE) Nigeria (South-East Zone)	14-05-2007
62	Meritorious and Appreciation Service Award	Traditional Council of Ndi Eze Igbo N'Uzo Ije in conjunction with Ohanaeze Ndi Igbo Business Council	May, 2007
63	Certificate of Honour	Micronutrient Forum Steering Committee in collaboration with Ministry of Health, Istanbul, Turkey	16-04-2007
64	Fellowship Award	Federal College of Complementary and Alternative Medicine (Alternative & Traditional)	04-04-2007
65	Honorary Fellowship	The Nigerian Institute for Biomedical Engineering (NIBE)	April 2007
66	Merit Award	Malaria Summit Group (MSG)	March 2007
67	Diamond Award	Leadership and Followership Development Centre (LEFODEC)	29-03-2007
68	Woman of the Year 2006/2007	WODEF and Today's Woman Media Group	29-03-2007
69	Model Nigerian Leadership Award	Catholic Women Organisation (C.W.O), Stella Maris Catholic Parish, Abayi–Aba, Abia State	25-03-2007
70	Selfless Service to Humanity Award	Catholic Diocese of Nnewi, Anambra State	11-03-2007
71	Award of Excellence	Evangelical Church of West Africa (ECWA) and Soldiers of the Cross	07-03-2007
72	ITWA Merit Award Certificate	Igbo Traders Welfare Association (ITWA), Lagos	24-02-2007
73	Award of Excellence	Foam Manufacturers' Group of Manufacturers' Association of Nigeria	21-02-2007
74	Merit Award for Excellence	Institute of Industrialists and Corporate Administrators	31-01-2007
75	Woman of Distinction Merit Award (WODMA 2006)	Trailblazers Magazine	Dec.2006
76	HURINET Award for Integrity	HURINET Awards 2006	13-12-2006
77	Africa Independent Achiever's Meritorious Award	A.P.A World Communication in Collaboration with Africa Independent Magazine	Dec. 2006

	AWARD	AWARDING BODY	DATE
78	Merit Award	Lagos State Medicines Dealers Association	Dec. 2006
79	Leadership Model Award	Igbo Peoples Action Congress (IPAC)	09-12-2006
80	Merit Award	Pest Control Association of Nigeria (PECAN)	06-12-2006
81	Gold Awards	Daughters Of Dominion (DOD), Love Base Assembly, FESTAC Town, Lagos	02-12-2006
82	Nigerian Muslim Merit Award, NIMMA	Nigerian Muslim Association	Nov. 2006
83	Merit Award	National Christian Association of Nigeria (CAN), Women's Wing	Nov. 2006
84	Outstanding National Service Award	Awka Development Union, Lagos Branch	25-11-2006
85	Merit Award	The Nigerian Institute of Quantity Surveyors (NIQS), Abuja	25-11-2006
86	Humanitarian Award	United Progressive Youth Vanguard	18-11-2006
87	Unique Woman Achiever Award	Nnewi Improvement Union (NIU), Women Wing, Lagos	18-11-2006
88	Girl Child Motivator Award 2006	Child's Life International Fund Foundation	15-11-2006
89	Award of Excellence	Gender and Development Action, Abuja	15-11-2006
90	Award for Pride of Nigerian Women	Women Advancement for Economic & Leadership Empowerment in Africa (WAELE/ARCELFA), Abuja	27-10-2006
91	Award of National Icon	The Career and Human Development Initiative (An Arm of CACSA, OOU)	21-10-2006
92	Merit Award	Nigerian Community in Cote D'Ivoire	Sept. 2006
93	The Most Outstanding Personality of the Year 2005/2006	Department of Business Administration Students, University of Lagos	Sept. 2006
94	Merit Award	National Postgraduate Medical College of Nigeria	11-09-2006
95	Award of Excellence	Lagos State Indigenes Association, Abuja	02-09-2006
96	Award for Excellence	Nigerian Institute of Physics (NIP)	17-08-2006
97	Award of Excellence	St. George's Ambulance Foundation Obafemi Awolowo University Chapter, Ile-Ife	10-08-2006

	AWARD	AWARDING BODY	DATE
98	Grand Ambassador of Pharmacy Award	Nigerian Association of Industrial Pharmacists	09-08-2006
99	Merit Award	Nigerian Institute for Food Science and Technology (NIFST)	08-08-2006
100	Award of Humanitarian Services	Nigerian Universities Accounting Student Association (NUASA)	20-07-2006
101	Excellent Merit Award	National Council of Muslim Youth Organisations (NACOMYO), Lagos	15-07-2006
102	Award of Excellence	Diabetes Association of Nigeria (DAN)	04-07-2006
103	1960–2005 Champion of Excellence Award	Oha Na Eze Ndi Igbo, South Korea	25-06-2006
104	Distinguished Woman of the Year 2006	Destiny Broadcasting Network (DBN)	25-06-2006
105	Merit Award	Otu Umunne Cultural Organisation, Inc. Atlanta, Georgia, USA	25-06-2006
106	2005 Peabody Award	University of Georgia, USA	24-06-2006
107	Woman of Valor Award 2006	Nigerian Women Association of Georgia, (NWAG), USA	24-06-2006
108	Merit Award	Institute for Agulu Development, Atlanta Chapter, USA	24-06-2006
109	Professional Pharmacy Service Award	Association of Nigerian Pharmacists of America, Atlanta Chapter	24-06-2006
110	A Key to Eket	Eket Local Government Area, Akwa Ibom State, Nigeria	01-06-2006
111	Merit Award	The Nigerian Institute of International Affairs	June 2006
112	Distinguished Service Award	Pharmaceutical Society of Nigeria, Benue State Branch	May 2006
113	Award of Excellence	Igbo Community Development Association (ICDA), Ibadan, Oyo State	07-05-2006
114	Meritorious Award	Diocese of Oji River (Anglican Communion)	May 2006
115	Diamond Award for Professional Excellence	Healthlink Magazine, Lagos	May 2006
116	Most Inspiring Leadership of the Year 2005	Excellence Recognition Awards	May 2006
117	Merit Award	Directorate of Naval Intelligence, Nigeria	April 2006
118	The Distinguished Nigerian Woman of Merit Award (2006)	Complete Success Magazine, Lagos	29-04-2006

	AWARD	AWARDING BODY	DATE
119	TESI Star Role Model Award	Teens Empowerment & Salvage Initiative (TESI), Lagos	16-04-2006
120	Award of Acclaimed Technocrat	Nigeria Television Authority Channel 5, Awka, Anambra State	31-03-2006
121	True Motherhood Award	Colostrum International (NGO), Lagos	26-03-2006
122	EYES Distinction Award	Early Years Exposure to Science (EYES) in Nigeria	10-03-2006
123	Woman of the Year 2006	Ada Nsukka Association of Nigeria	Feb. 2006
124	Merit Award	Old Aguata United (OAU), Abeokuta, Ogun State Branch	25-02-2006
125	Fellowship Award	Institute of Industrialists and Corporate Administrators, Nigeria	14-02-2006
126	Fellowship Award	Federal College of Education (Technical), Umunze, Anambra State	Dec. 2005
127	Merit Award	Inner Wheels Club of Aba, Abia State	Dec. 2005
128	Award of Excellence	Integrated World Services (IWS)	Dec. 2005
129	ICON of Hope Award	Royal Charity Foundation (NGO)	28-12-2005
130	Award of Excellence Eastern Women Role Model	Craft House Communication Ltd.	21-12-2005
131	A Star Performance Award	Ateko Women Association (AWA), Lagos	17-12-2005
132	Merit Award	Nigerian Medical Association, FCT, Abuja Branch	14-12-2005
133	Merit Award	Association of Nutrition Science Students, Department of Human Nutrition, University of Ibadan, Oyo State	12-12-2005
134	Ohanaeze Outstanding Achievers Award	Ohanaeze Ndigbo Ondo State Chapter, Akure	08-12-2005
135	An Icon of Excellence Award	The African Cultural Institute and Zenith Bank Plc	08-12-2005
136	Humanitarian Excellence Award of "Transparency & Achievement"	Hope Alive Humanitarian Network (HAHUNET), Jos	05-12-2005
137	Meritorious Award 2005	St. Michael's Military Catholic Church, Apapa, Lagos	04-12-2005
138	Award of Excellence	Nigerian Association of Science Students (NASS), Federal University of Technology Akure, Ondo State	Dec. 2005

	AWARD	AWARDING BODY	DATE
139	African Virtuous and Entrepreneurial Women Merit Award 2005	African Biographical Network	Dec. 2005
140	XCEL Award of Excellence 2005	XCEL Magazine Ltd	Dec. 2005
141	Life Achievement Award	House on the Rock, Abuja	Dec. 2005
142	Award of Excellence	Imo Women, Imo State	02-12-2005
143	Special Award	Vanguard for Democratic Youth, Abuja	01-12-2005
144	Excellence Award	National Association of Government Approved Freight Forwarders (NAGAFF), Lagos	30-11-2005
145	The Zik Prize in Leadership	Public Policy Research and Analysis Centre, Lagos, Nigeria	29-11-2005
146	Certificate of Award of the 2005	Blue-Ribbon Drug Safety Promotion, Ministry of Economic Planning, Kaduna State	29-11-2005
147	Merit Award	International Criminal Police Organization (ICPO) – Interpol	14-11-2005
148	Ambassadorial Award	African Women's Cancer Awareness Association, USA	05-11-2005
149	Midwife of the Health of the Nation Award	Nigerian Bar Association, Aguata Branch	Nov. 2005
150	Most Innovative Director Award	Federal Government College, Ijanikin, Lagos	Oct. 2005
151	Achievement Award	The International Nature Conservation & Environment Programme	Oct. 2005
152	Award of Excellence	Umuahia Diocesan Council of Catholic Women Organisation (UDCCWO), Mater Dei Cathedral	23-10-2005
153	Award for Outstanding Service to the Nation	National Union of Benue State Students (NUBESS)	22-10-2005
154	Stewardship Excellence Award	Women Trafficking and Child Labour Eradication Foundation (WOTCLEF)	12-10-2005
155	Homeland Ambassador Award	Board of Directors and the Executive of The Nigerian Union, USA	09-10-2005
156	Pride of Woman	Catholic Women Organisation (CWO) of Holy Trinity Catholic Church, Maitama, Abuja	

	AWARD	AWARDING BODY	DATE
157	Excellence Award	NDIGBO, Lagos, Nigeria	09-10-2005
158	Good Ambassador of Family Award 2005	Family Life Organisation (FAMILO), Abuja, Nigeria	29-09-2005
159	Distinguished Merit Award	Rotary Club of Apo (FCT), District 9130, Abuja, Nigeria	Sept. 2005
160	Achiever and Peace Advocate Award (APAD)	Peace Education Centre, Obafemi Awolowo University, Ile-Ife	24-09-2005
161	Certificate of Recognition	United States Patent and Trademark Office, Johannesburg, South Africa	22-09-2005
162	Merit Award	Students Against Destructive Decisions (SADD)	15-09-2005
163	Woman of Honour	National Council of Women's Societies (NCWS), Nigeria	05-08-2005
164	Selfless Service to Humanity	Youth Democratic Initiative in Collaboration with International Republican Institute	22-07-2005
165	ECOMSAN Merit Award 2005	Environmental Control and Management Students' Association of Nigeria (ECOMSAN), Obafemi Awolowo University, Ile-Ife, Nigeria	15-07-2005
166	Distinguished Award as a Role Model of Nigerian Society	Ahmadu Bello University Students' Union Government (ABUSUG), Zaria, Nigeria	15-07-2005
167	Women Achievers Award 2005	Women's Wing of Christian Association of Nigeria (WOWICAN), Lagos State Chapter, Lagos, Nigeria	08-07-2005
168	Role Model Award	Halifield School, Lagos, Nigeria	23-06-2005
169	Merit Award	Nigerian-British Chamber of Commerce, Nigeria	28-05-2005
170	An Award Par Excellence in Children's Welfare	Kiddies Loveworld, Abuja, Nigeria	27-05-2005 27-05-2005
171	Merit Award	Polytechnic Female Staff Association, Oko, Nigeria	
172	Merit Award	Nigerian Institute of Management, Benin City	25-05-2005
173	PHCCIMA Merit Award 2005	Port Harcourt Chamber of Commerce, Industry Mines and Agriculture (PHCCIMA), Port Harcourt, Rivers State, Nigeria	19-05-2005

	AWARD	AWARDING BODY	DATE
174	Honorary Doctor of Science Degree (DS Honoris Causa)	Federal University of Technology, Owerri (FUTO), Nigeria	14-05-2005 14-05-2005
175	Diamond Leadership Award	Pan Ndi-Igbo Foundation, USA, Inc.	07-05-2005
176	Council of Peers Award for Excellence (CPAE)	Council of Peers, Aba, Abia State, Nigeria	
177	Quintessence Award 2004	New Jersey General Assembly, USA	30-04-2005
178	Certificate of Honour	African Institute of Women and Gender Studies, Uyo, Akwa Ibom State, Nigeria	23-04-2005
179	Integrity Award	Methodist Church, Owerri, Nigeria	14-04-2005
180	Award of Excellence	Catholic Youth Organisation of Nigeria (CYON), Uyo Diocese	10-04-2005
181	Excellence in Public Service Administration Award	Business Reports International Merit Award (BRIMA)	09-04-2005
182	Award of Excellence	Truth Talk Foundation, Asaba, Delta State, Nigeria	02-04-2005
183	Integrity Legacy Award	Transparency & Integrity Foundation, Kaduna, Nigeria	April 2005
184	Executive Performance Award	Centre for Presidential Studies Igbinedion University, Okada, Edo State	23-03-2005
185	Award of Excellence	Newcare Home Health Services, Inc., USA	17-03-2005
186	Award For Excellence	International Inner Wheel, Aba, Nigeria	26-02-2005
187	Amazon Mother of the Year Award.	Africa Women's Voice (AWV)	18-02-2005 17-02-2005
188	Outstanding Fellows 2004 Award	Pharmaceutical Society of Nigeria (PSN)	Nov. 2004
189	Nation Builders Award	Counseling Agency & Galaxy Television, Lagos, Nigeria	
190	Merit Award	Pentecostal Fellowship of Nigeria	Dec. 2004
191	Amazon of Integrity	National Council of Women Society – NCWS	Dec. 2004
192	Gafem Awards 2004 for Best Grassroots Personality	Sicoplus Media	14-12-2004 Dec. 2004
193	Distinguished Merit and Achiever's Award	Nigeria Youth Organisation (NYO), Abuja, Nigeria	

	AWARD	AWARDING BODY	DATE
194	Merit Award for Health Leadership	Nigeria Federation of Catholic Students (NFCS)	11-12-2004
195	Excellence Award in Humanity Service & Nation Building	Association of Former Local Government Chairmen and Councilors in Nigeria (AFLOG), Abuja, Nigeria	10-12-2004
196	Distinguished Eminent Lioness Award	University of Nigeria Alumni Association, Lagos, Nigeria	07-12-2004
197	Most Outstanding Public Servant in Nigeria	Xclusive Magazine, Nigeria	02-12-2004 Nov. 2004
198	Certificate of Honour	Queen of Martyrs Catholic Church, New Lugbe, Sacred Heart Parish, Airport – Abuja	
199	Award of Excellence	Catholic Women Organisation (C.K.C Parish, Kubwa), Abuja	28-11-2004
200	Merit Award	Pharmaceutical Society of Nigeria, Abuja Branch	Nov. 2004
201	Merit Award	ECWA Student Ministry Association Forum (ESMAF), Abuja 2004	Nov. 2004
202	Merit Award for Excellence in Service	Students' Union Government, University of Nigeria, Enugu Campus	Oct. 2004
203	2004 Prestigious Woman of Distinction Award The African Virtuous	African Woman International Merit Award (AHUDA Awards 2004), Abuja, Nigeria	Oct. 2004
204	Leadership Gold Award	African Gold International Communication	Oct. 2004
205	Merit Award	Fellows of the Institute of Management & Technology (FIMT), Enugu	30-10-2004
206	Merit Award	Institute of Directors (IOD), Lagos, Nigeria	30-10-2004
207	Most Exemplary Women Leader Award	Women in Support for Development (WOSUD)	27-10-2004
208	Merit Award	Nigerian Institute of Food Science and Technology (NIFST)	14-10-2004
209	Visionary Award	First VISIONigeria	12-10-2004
210	Award of Relevance	Guidance and Counselling Section of the Faculty of Education, Ahmadu Bello University, Zaria, Nigeria	01-10-2004
211	Human Restoration Award	WOTCLEF, Rivers State, Nigeria	Oct. 2004

	AWARD	AWARDING BODY	DATE
212	EarthWATCH Award for Unique Woman of the Year	EarthWATCH Awards 2004	Sept. 2004 Sept. 2004
213	Excellence in Administration Award.	National Union of Chemical Footwear, Rubber, Leather and Non-Metallic Products Employees (NUCFRLANMPE), Lagos, Nigeria	
214	Friends Of Jesus (FOJ) Award	Serenity International, Abuja, Nigeria	29-09-2004 25-09-2004
215	Award of Excellence	Catholic Nurses' Guild of Nigeria (CNGN)	
216	Certificate of Merit for Dedication, Objective & Transparency	BUKAR NLARAKU	21-09-2004 09-09-2004
217	Merit Award for Outstanding Personality Lecture Series	Students' Historical Society of Nigeria, University of Ibadan Chapter	08-09-2004
218	National Integrity Award	Pharmaceutical Association of Nigerian Students (PANS)	
219	Merit Award	National Institute for Policy & Strategic Studies, Kuru, Nigeria	31-08-2004
220	Merit Award	Apostle Paul Gospel Crusade (Rebirth of a National Conference, 2004)	23-08-2004 Aug. 2004
221	Heroes Award	Academic Staff Union of Universities, Lagos State University Branch, Lagos, Nigeria	
222	Distinguished Service Award	Nigerian Association of Hospital and Administrative Pharmacists	24-08-2004
223	Merit Award	Rotaract Club District 9120, Nigeria	13-08-2004 07-08-2004
224	Brand Personality of the Year (Female) Award	The Pacesetters, Department of Mass Communication, Moshood Abiola	
225	Merit Award as "Motivator of Nigerian Youths"	Polytechnic Abeokuta National Association of Nigerian Students (NANS)	07-08-2004
226	Role Model Award	Association of Nigeria Women in the Gambia (ANWIGAM)	06-08-2004

	AWARD	AWARDING BODY	DATE
227	Award for Combating Counterfeit Medicine	Newsgate Communications Limited	06-08-2004 31-07-2004
228	Outstanding Achiever's Award	Nigerian Army Officers' Wives Association (NAOWA)	
229	The Best Public Personality of the Year (Female)	Encomiums Magazine, Nigeria	23-07-2004 09-07-2004
230	Merit Award for Excellence in Health Administration	Nigeria Union of Journalists (NUJ), Enugu, Nigeria	
231	Vice-Chancellor's Distinguished Service Award	University of Nigeria, Nsukka	18-06-2004 June 2004
232	Transparency Award	The Campaign for Positive Change in Africa (CPC)	
233	Certificate of Recognition	Institute of Industrialists & Corporate Administrators	June 2004
234	Excellence in Christ in Governance Award	Ecumenical Apostolic Church Diocese, USA (Received in Abuja)	10-06-04
235	African Peace Award	The Aguata-Orumba Women Association, Southern California, USA	05-06-2004
236	African Civic Responsibility Award 2004-2005	The African Times – USA	22-05-2004 21-05-2004
237	Award of Excellence	Lagos Archdiocesan Council Catholic Women Organisation (LACCWO)	13-05-2004
238	Dr Kwame Nkrumah Africa Leadership Awards – 2004	Intra-West Africa Communications Ltd. (publishers of West Africa International Magazine), Ghana	
239	Merit Award for Outstanding Contribution to the Accountancy Profession	The Institute of Chartered Accountants of Nigeria	May 2004 April 2004
240	Award for Excellence	Rotary Club of Ikoyi, District 9110, Nigeria	
241	Certificate of Merit	Queen of the Holy Rosary Parish, Ugwuagor, Abakpa Nike, Enugu	26-04-2004
242	Distinguished Leadership Merit Award	Zone 7 Police Community Relations Committee, Abuja, Nigeria	25-04-2004
243	The Exemplary Nigerian Award for Transparency & Incorruptibility	New Direction Initiative	06-04-2004

	AWARD	AWARDING BODY	DATE
244	Award of Excellence	The Student Union Government House of Parliament, University of Jos, Nigeria	01-04-2004
245	The African Woman	WOTCLEF	01-04-2004
246	1st Best Consumer Sensitive Government Agency	Consumer Advocacy Forum of Nigeria (CAFON)	April 2004
247	Award of Excellence Recognition Award	Excellent Women International Ministries (EXWIM)	30-03-2004
248	Nady National Award 2004	African Society for Toxicological Sciences (ASTS), Baltimore, Maryland, USA	
249	Award of Excellence,	National Association of Democratic Youths, Kaduna, Nigeria	25-03-2004
250	Outstanding Public Administrator (OPA) of the Year 2004	National Universities Association of Management and Business Students (NUAMBS) – University of Jos Branch, Jos, Nigeria	23-03-2004
251	Merit Award	University of Calabar (UNICAL), Calabar, Nigeria	20-03-2004
252	Excellence in Public Administration, Accountability & Integrity Award	Federal University of Technology, Owerri (FUTO), Nigeria	12-03-2004 04-03-2004
253	Saviour of the Nation's Health Award	National Association of Patent and Propriety Medicines Dealers (NAPPMED), Maiduguri Chapter, Bauchi State, Nigeria	
254	Chief Safeguard of the Nation	Nigerian Association of Patent & Proprietary Medicine Dealers, Borno State, Nigeria	26-02-2004
255	Gold Medal Merit Award for Excellence and Peace Performance	International College of Chaplains, Imo State, Nigeria	25-02-2004
256	Award of Honour	St. Dominic's Catholic Church, Yaba, Lagos	25-02-2004
257	Consumer Excellence Awards 2003	All Nigerian Consumer Movements' Union (ANCOMU), Lagos, Nigeria	24-02-2004
258	Merit Award	Association of Resident Doctors, University Teaching Hospital (JUTH), Jos, Nigeria	21-02-2004

	AWARD	AWARDING BODY	DATE
259	Honorary Award	National Union of Anambra State Students (NUASS), University of Ibadan Chapter, Ibadan, Nigeria	10-02-2004
260	Certificate of Honour	Ifite Progressive Union , Ifite Nanka, Orumba North L.G.A.	07-02-2004
261	Excellence Award in Leadership and Service.	Mboho Mkparawa Ibibio, Uyo, Akwa Ibom State, Nigeria	31-01-2004
262	Great African Merit Awards (GAMA 2003)	Complete Success Magazine	02-01-2004 27-12-2003
263	Excellent Service Award	Nigeria Union of Journalists, OSBC Chapel	
264	FCS (Fellow Council of Scholars) Award	Oputa Chambers of Justice, Faculty of Law, University of Calabar, Calabar, Nigeria	20-12-2003
265	UNMSA Executive Excellence Award	University of Nigeria Medical Student Association (UNMSA), Nsukka, Nigeria	18-12-2003
266	The Nigerian Health Achiever of the Year	Nigerian Achiever Awards 2003	13-12-2003 08-12-2003
267	Appreciation Award	Odunaike Memorial Lecture 2003 Planning Committee, Foursquare Gospel Church in Nigeria	
268	Award of Excellence	National Council of Women's Societies Nigeria, Lagos Branch	28-11-2003
269	The Humanitarian Award 2003	Handicapped Affairs Association of Nigeria	Nov. 2003
270	PAF Integrity Award	PAF	June 2003
271	Award of Excellence	Nnamdi Azikiwe University Medical Students Association (NAUMSA), Awka, Anambra State, Nigeria	Nov.2003
272	Merit Award of Excellence	University of Nigeria Alumni Association, Ogun State Branch, Ogun State, Nigeria	Nov. 2003
273	Humanitarian Award	Nigeria Red Cross Society, Island Division, Lagos, Nigeria	Nov. 2003
274	Merit Award	National Women Peace Group (NAWOPEG)	Nov. 2003
275	The Nigerian Health Achiever of the Year	Nigerian Achievers Awards 2003, Abuja	29-11-2003

	AWARD	AWARDING BODY	DATE
276	American Association of Nigerian Pharmacists Award	American Association of Nigerian Pharmacists, USA	28-11-2003
277	Merit Award	Howard University Washington DC, USA	28-11-2003
278	Fellowship of the Pharmaceutical Society of Nigeria (FPSN)	Pharmaceutical Society of Nigeria (PSN), Nigeria	19-11-2003 19-11-2003
279	2003 Rimson Risk Management Award	Risk & Insurance Management Society of Nigeria (RIMSON)	
280	Honorary Fellowship of the Nigerian Metallurgical Society	Nigerian Metallurgical Society	04-11-2003 Oct.2003
281	Award for Excellence	Queen of the Rosary Secondary School, Nsukka (Old Girls' Association)	
282	Role Model Award	Chemical Society of Nigeria (CSN)	31-10-2003
283	Christian Integrity Award 2003	The Gospel Music & Arts Festival (GMAF), Surulere, Lagos	26-10-2003
284	Most Outstanding Female Administrator	National Association of Nigerian Students (NANS)	18-10-2003
285	Hope for Humanity Award	Rotary Club of Tin Can Island, R-1, District 9110, Nigeria	Sept. 2003
286	Annual Merit Award 2003	Pharmaceutical Society of Nigeria, Ebonyi State Branch	20-09-2003
287	NIPR Merit Award for Distinguished National Service	Nigerian Institute of Public Relations (NIPR), Anambra State Chapter. 10th Anniversary, 2003	18-09-2003
288	Award of Professional Excellence	Inner Wheel Club of Garki FCT District 913 International	13-09-2003
289	The Mirror of Tourism in Nigeria	The Youth Tourism and Hospitality Club (YOUTHAC), University of Jos	13-09-2003
290	Award of Excellence in Administration	Graduate Student Association of Ibadan (GSAN), University of Ibadan Chapter	26-08-2003
291	Ambassador of Peace Award	Inter-religious & International Federation for World Peace, Nigerian Chapter	23-08-2003
292	Patriot of Honour Award	International Centre For Development Policy	21-08-2003
293	Merit Award	Association of Lady Pharmacists	21-08-2003

	AWARD	AWARDING BODY	DATE
294	Award of Excellence	Royal Avan Foundation	12-08-2003
295	Vocational Gold Service Award	Rotary Club of New Haven, Rotary Int'l District 9140, Nigeria	05-08-2003
296	Distinguished Catholic Professionals Award	Young Catholic Professionals, Church of Assumption, Falomo, Lagos	26-07-2003
297	Paul Harris Fellow Award	Rotary International District 9110, Nigeria	26-07-2003
298	Award of Excellence	Female Ministers' Forum (FMF) International	25-07-2003
299	Humanitarian Service Award	Rotaract Club of the University of Nigeria Enugu Campus	11-07-2003
300	Honorary Award	The Dokita Editorial Board, University College Hospital, Ibadan	28-06-2003
301	Award for Service to Society	St. Paul's Cathedral, Nsukka	24-06-2003 12-06-2003
302	Best FCT Woman of the Year 2002	Ministry of Federal Capital Territory, Health Services Development	
303	National Service Award	Rotaract District 9110, 9120, 9130 & 9140 Nigeria, Owerri	27-05-2003
304	NUJ Merit Award	Nigeria Union of Journalists, Plateau Council	10-05-2003
305	Fellowship Award	IAEAA-1400 Vienna- Austria	10-04-2003
306	Award of Excellence	Coalition for Women in Democracy in Nigeria	10-04-2003
307	Honorary Award	National Association of Medical Laboratory Sciences Student (NAMLSS), Sheraton, Abuja	08-04-2003
308	Woman of the Year 2002	The American Biographical Institute Board of International Research (ABI)	31-03-2003
309	Best Democrats Award	Movement for the survival of Democracy in Nigeria (MOSDIN), Abuja	27-03-2003
310	Business Times Person of the Year Award (2002)	Daily Times of Nigeria, Plc	25-03-2003
311	Eko FM Listeners' Person of the Year (2002)	Radio House, Lateef Jakande Road, Agidingbi, Ikeja, Lagos	24-03-2003
312	Honorary Award	Association of General and Private Medical Practitioners of Nigeria	18-03-2003

	AWARD	AWARDING BODY	DATE
313	Rare Gems 2003 Award	Women's Optimum Development Foundation (WODEF) & United Nations Development Fund for Women (UNIFEM)	16-03-2003
314	Icon of Good Leadership	National Association of Nigerian Students (NANS)	08-03-2003
315	African Youth Achiever's Award	Gold Image Communications Ltd.	01-03-2003 21-02-2003
316	Distinguished Service Award	University of Lagos (UNILAG) Alumni Association, Cross River State Branch	
317	Award of Excellence	Federal Medical Centre Centenary Anniversary, Owerri	21-02-2003
318	Total Quality Leadership Award	African Institute for Democracy & Good Governance (AIDEGOG)	08-02-2003
319	The Eagle Award	Transcoast London Limited	23-01-2003
320	Cerany Ethics Award	Campaign for Ethics Rebirth Among Nigeria Youths	Dec. 2002
321	Award of Honour	Nigerian Association of Academic Pharmacists	Dec. 2002
322	Recognition Award	Pharmaceutical Manufacturers Group of the Manufacturers Association of Nigeria (PMG-MAN)	April 2002
323	Gender Award 2002	Gender Research Women Emancipation and Empowerment Development	May 2002
324	Certificate of Honour	WEMFA	June 2002
325	Award of Excellence	Agulu Transition Committee (ATC), Agulu, Anaocha L.G.A., Anambra State	Dec. 2002
326	NDLEA Annual Merit Award for Excellence	National Drug Law Enforcement Agency, Lagos, Nigeria	27-12-2002
327	Merit Award	Nigerian Bar Association, Abuja Branch	19-12-2002
328	Distinguished Administrators' Award for Administrative Excellence	Nigeria Union of Journalists (NUJ), Oyo State Council	19-12-2002 18-12-2002
329	Merit Award	Nigeria Television Authority (NTA) 2, Victoria Island, Lagos	
330	Honorary Fellowship Award	Federal Polytechnic Offa, Kwara State	14-12-2002
331	Excellence in Public Service Administration	Nigerian Institute of Management (NIM), Anambra State Chapter, Awka	14-12-2002

	AWARD	AWARDING BODY	DATE
332	National Service Merit Award	Obafemi Awolowo University Alumni Association (Abuja Branch)	13-12-2002
333	Crime Fighters' Excellence Award	Crime Fighters – Nigeria Police Force	12-12-2002 12-12-2002
334	Life Fellow of the Institute	Institute of Journalism & Management, Enugu	
335	Award of Excellence	The Standing Committee of Medical Education & Health, Medical Student Association ABUTH, Tudunwada, Kaduna	12-12-2002
336	Female Achiever for the Year 2002	City People Magazine	07-12-2002 02-12-2002
337	Award of Excellence	Nigerian Institute of Public Relations, Ogun State Chapter	
338	African Woman Corporate Giant Award	African Woman International Communication Ltd	29-11-2002
339	African Youth Achievers Award 2002	Planning Committee, African Youth Achiever Award 2002	28-11-2002
340	Award of Excellence	Nanka Patriotic Union, Lagos Branch	25-11-2002
341	Honorary Merit Award	Association of Resident Doctors Gwagwalada Specialist Hospital, Abuja	16-11-2002
342	Amazon Award	Mixed Media Communication Ltd	13-11-2002
343	Model Presentation	Association of Anambra State Development Union	07-11-2002
344	2002 Vocational Merit Award	Rotary 2002/2003 International District 9140, Rotary Club of Ogbor Hill, Aba	01-11-2002
345	Leadership Award	Leadership Watch	26-10-2002
346	Merit Award	National Universities Association of Management Students, University of Calabar	18-10-2002
347	Juli Award	Annual Lecture and Distinguished Pharmacy Award Ceremony by Juli Plc	10-10-2002
348	Indomitable Spirit Award	People Democratic Party, Wuse, Abuja	07-10-2002
349	Vocational Service Award	Rotary Club of Asokoro, District 9130, Nigeria	05-10- 2002
350	African Woman International Merit Award (AWIMA)	African Woman International Magazine	Oct. 2002

	AWARD	AWARDING BODY	DATE
351	Grand Defender of Faith Merit Award	Anglican Diocese of Maiduguri	29-09-2002 28-09-2002
352	Award of Honour	The Guild of Medical Directors, GMD (Abuja Chapter)	
353	Honorary Award	National Institute for Cultural Orientation (NICO)	26-09-2002
354	One of the Top 20 Chief Executives in Corporate Nigeria	Vanguard Media	17-09-2002 11-09-2002
355	Merit Award	Nigerian Medical Association, Anambra State Branch	
356	Professional Woman of Distinction Merit Award	Center for Criminal Justice Reform & Citizen Awareness	11-09-2002
357	Prestigious Africa International Award of Merit 2002	West Africa International Magazine in collaboration with African Refugees Foundation and Liberian Embassy, Nigeria	05-09-2002
358	National Media Award	Nigeria Union of Journalists, Garki, Abuja	Sept. 2002
359	Merit Award	Nigerian Institute of Management (NIM), Abuja Branch	29-08-2002
360	Contemporary Who is Who 2002/2003 Award	International Who is Who of Professional & Business Women, Nigeria	05-08-2002
361	Honorary Award	Food & Drug Administration and Joint Institute for Food Safety and Applied Nutrition, USA	22-07-2002
362	Contemporary Age Honours	Contemporary Age Magazine	20-07-2002
363	Woman of the Year	International Foundation for Excellence (IFEX), Lagos	July 2002
364	Distinguished Executive Award	Corporate Affairs Commission (CAC)	28-06-2002
365	Vocational Service Award	Rotary Club of Enugu-Capitol	13-06-2002
366	Woman in Service Award	Medical Women Association of Nigeria, Enugu State	25-05-2002
367	Award of Excellence	Nigeria Union of Journalists (Abuja State Council)	22-05-2002

	AWARD	AWARDING BODY	DATE
368	Prime International Corporate Women in Leadership Merit Award	Prime International Communications Ltd	11-05-2002
369	Merit Award	People State and Resources (PSR)	11-05-2002
370	Excellence Performance Award	Nigerian Union of Journalists (Anambra State Council)	26-04-2002
371	Award of Excellence	The President, PANS, Obafemi Awolowo University Branch, Ile-Ife	19-03-2002
372	Special Merit Award	National Association of Igbo Youths	22-02-2002
373	Award of Excellence as a Milestone	Centenary Anniversary Committee, Federal Medical Centre, Owerri Imo State	08-02-2002
374	IBC's 21st Century Award for Achievement	International Biographical Centre (IBC) Cambridge, England	23-01-2002
375	Woman of the Year 2002	The American Biographical Institute Board of International Research	Jan. 2002
376	Certificate of Excellence	Igbo Youths Association, Enugu	26-12-2001
377	Award of Excellence	College of the Immaculate Conception (CIC), Old Boys' Association, Enugu	08-12-2001
378	Distinguished Alumnus Award	The University of Nigeria Alumni Association, Nsukka	07-12-2001
379	Honours Award	Anambra State Development Foundation	Aug. 2001
380	The Woman of Merit Gold Award	People State and Resources (PSR) Magazine, Nigeria	04-07-2001
381	Merit Award	Pharmaceutical Society of Nigeria, Enugu Branch	Nov. 1998
382	International Pharmaceutical Federation Award	International Pharmaceutical Federation, Hague	Sept. 1998
383	USA Congress Award	Family Health International (10th International Congress on AIDS)	Aug. 1994
384	Pharmacological Society of Canada's Congress Award	12th International Congress of Pharmacology, Montreal, Canada	July 1994
385	Fellowship Award	Commonwealth Post Doctoral Fellowship	1988/89
386	Vice Chancellor's Postgraduate and Research Leadership Prize	19984/85 and 1985/86 Academic Sessions – Faculty of Pharmaceutical Sciences	1985
387	Kingsway Prize for the Best First Year Pharmacy Student	Kingsway, Nigeria	1975
388	Undergraduate Scholarship	Federal Government of Nigeria	1974
389	Post Primary Scholarship	Eastern Nigeria Government	1967

APPENDIX 25 – A Few Examples of Comments Posted in National Dailies



• Akunyili

WOMAN IN THE NEWS

Handmaiden Of Compassion

"The casualties of war are not only those who went to war, but also those they left behind."

- J.P. Clark (*The Casualties*)

Good Samaritans, they say, are like sunflowers, because their deeds are born of light. Thus, it was with joy that disabled veterans of the Nigerian civil war received a cheque of N3million from the Director General of the National Agency for Food and Drug Administration and Control (NAFDAC), Professor Dora Akunyili, recently at their Oji River Camp in Enugu.

The money was donated by a group of philanthropic organisations, which include De-United Food Industry Limited and Fidson Healthcare Company Limited. However, Akunyili had to be present because an individual who chose to be anonymous had also donated money to the disabled war veterans as his/her own way of celebrating Akunyili's recent award that was given to her by Silverbird Communications.

The three donors who were able to jointly donate N3million for the 50 families present at the Camp expect the money to be shared equally among the families, which means that each family would get N60,000.

At the presentation of the cheque, the woman who has led Nigeria out of the nightmare of being a

By Michael Uchebuaku

haven for fake and adulterated drugs said: "These used to be able-bodied men who suddenly became beggars as a result of the civil war. They suddenly lost their hands, some don't have legs, yet they have families."

What compassion did the NAFDAC helmswoman show towards the disabled war veterans! What pathos does the plight of the Biafran war handicapped casualties inspire in the heart of every well meaning Nigerian, which then calls for urgent and positive action towards alleviating their suffering!

Indeed, the action of the erudite university professor is exemplary and calls for imitation by all and sundry.

Akunyili has been a role model to Nigerians in many ways. She is widely regarded as a genuine national heroine not only because of her courage in fighting for the good health of Nigerians but also for her corporal acts of mercy towards the less privileged in the society.

This is not the first time the Amazon of patriotism is thinking of providing relief to the disabled civil war veterans. In January this year, she had announced that she would donate N1million of her Silverbird award money to the amputees. She recalled as she presented the N3m cheque:

"During the award, I announced that the one million naira cash prize donated by Union Bank for the award would be given to the families of amputees of the last civil war, who are currently residing in a zinc shanty

encampment at Oji river."

During her acceptance speech at the presentation of the Silverbird award in Lagos, she had said: "Most people who pass that road would have seen the amputees begging for alms by the roadside. I wish to dedicate this award to our 224 brothers, sisters and children that died in the three painful and ill fated plane crashes we had in 2005. We pray that never again shall we experience such tragedies in such a quick succession."

The woman who has received over 300 awards and honours in the past four and a half years must be commended for her zeal to wipe the tears of this poor group of Nigerians.

"The generation of combatants that fought the civil war are in their middle age or older. Nigeria owes this generation the onus of providing some type of closure for the mayhem that they lived through in the epic struggle to keep Nigeria's territorial integrity whole. Not doing so could mean one of two things namely: that the civil war has really not ended or that its outcome is unworthy and irrelevant in nation building," says Okenwa Nwosu, an Igbo in diaspora.

There are still many disabled war veterans at the rehabilitation centre at Oji River in Enugu. Their condition is deplorable to say the least and all individuals and corporate bodies of goodwill would do well to lend a helping hand to these handicapped neighbours and end their awful existence as street beggars.

Africans embrace NAFDAC's fake drug campaign

By
GRACE YUSSUF

THE road to receiving an award by the Gabonese Pharmaceutical Federation was as tortuous as it was rewarding to Prof. Dora Akunyili. Frustrated by flight delays and cancellations, Akunyili, Nigeria's anti-fake drug campaigner, finally made her appearance at the recent Ninth African Pharmaceutical Forum in Libreville.

The NAFDAC's Director-General was invited to the Gabonese capital to receive the "Prix Gallien Afrique" or "Highest Achievement in Pharmaceuticals in Africa" award. The honour was in recognition of her fruitful campaign against fake and adulterated drugs in Nigeria and the West African sub-region.

"The recognition given me through the award is an honour not just to Nigeria but also an opportunity to bridge the division created by different languages that prevent us from working together to fight drug counterfeiting on the African continent."

"I cannot afford to reject this award because it is a big plus for our unity," she said. The campaign against fake and adulterated drugs in Nigeria has come a long way since April 2001 when Akunyili emerged the head of the National Agency for Food and Drugs Administration and Control (NAFDAC).

For more than three decades, the problem of fake and adulterated drugs had taken a dangerous dimension as previous efforts to contain the menace had failed. The consequence was the high death rate occasioned by the administration of unwholesome drugs, especially among women and children. Nigeria's reputation nosedived in the international pharmaceutical arena as confidence in the nation's health care system had been eroded.

The implications included treatment failures and development of drug resistance to ailments, especially infectious diseases and malaria.

As people died as a result of taking fake and adulterated drugs, legitimate pharmaceutical outfits were forced out of business due to unfair competition by fake drug manufacturers. As many local drug manufacturing firms ran out of business, several of their multinational counterparts were frustrated out of the country.

The fate of Boehringer, Sanofi, Merck, Boots and Pfizer comes to mind. But more worrisome was the fact that most made-in-Nigeria drugs were banned from other West African countries. The scope of drug counterfeiting was massive, including massive copying of original brands of most NAFDAC regulated products.

The result was that Nigeria became a dumping ground for fake and adulterated drugs, unwholesome foods, substandard cosmetics, chemicals and other related products.

"Nigeria was thus rated as one of the countries with the highest incidence of fake drugs in the world. The country also became the hub of fake and adulterated drug trafficking in sub-Saharan Africa," says an analyst.

A baseline study by NAFDAC shows that 68 per cent of drugs in Nigeria are unregistered. But all this is now history following NAFDAC's unrelenting war against the menace of fake and adulterated drugs. The ugly trend began to change when the agency started mopping up fake drugs in the country.

However, the campaign was not without stiff resistance from the drug barons and their accomplices. The mop-up exercise included sealing off of drugs shops, supermarkets and eateries as well as the closure of three major drug markets in Abuja in 2002, Kano in 2004 and Onitsha in 2007.

Akunyili said because of the heat on drug counterfeiters in Nigeria, many of them escaped to other African countries where they continued with their dastardly acts. To counter their activities, she said NAFDAC had to initiate the establishment of the West African Drug Regulatory Authorities Network (WADRAN). WADRAN is a forum where heads of drug regulatory authorities in the sub-region share strategies and experiences in the fight against drug counterfeiting.

Receiving her award, Akunyili said that the language barrier between Anglophone and Francophone Africans was negating the fight

against drug counterfeiting. According to her, the menace can only be tackled through effective cooperation between the two blocs.

"This network is an opportunity to create that synergy between French and English-speaking African countries, not just in ECOWAS but also in all of Africa."

Akunyili decried the attitude of some African political leaders whom she accused of encouraging drug counterfeiting by not allowing their regulatory authorities the free hand to perform their duties.

Without the support of such politicians, she said, the fight against fake drugs would not succeed.

Timoléa Francophone African country, when fake drugs were seized, the government ordered their immediate release.

"It, therefore, becomes necessary for us to work in concert so as to ensure that drug coun-



DR. DORA AKUNYILI, NAFDAC-D-G

terfeiters do not find a safe haven anywhere in the sub-region," she said.

Akunyili's observation was corroborated by her counterpart from Niger Republic, Dr. Rahanatou Gary, of the Pharmaceutical Association of Niger, said that the challenge of fake drugs was threatening the lives of citizens in her country.

She said that more than 70 per cent of drugs coming into that country were fake, adding that the government was not doing anything about the situation.

Gary alleged that the government had been encouraging fake drug merchants, "as they will claim that the business people are the ones that elected us into office."

"A typical case was in 2000 when some drugs were seized by the regulatory authority, but the president ordered their immediate release."

"These were stolen drugs from UNICEF, fake multivitamin drugs, machines for changing expiry dates and other drugs that were not supposed to be found in the country."

"Yet they were released by the government," Gary, therefore, called on pharmacists on the continent to cooperate and fight the scourge.

"With this kind of forum, bringing together both the English and French-speaking countries together, we will go along way," she said.

Analysts say the of problem of fake drugs in Nigeria and indeed on the continent is their sale in unregistered outlets.

Mr. Azubike Okwor, the President, African Pharmaceutical Forum, the Anglophone arm of the continental body, says the Federal Government should regulate the establishment of pharmaceutical outfits to ensure that they are registered.

He says the authorities are finding it difficult to fight the menace of drug counterfeiting because of the unregistered outfits.

According to Okwor, there are more than 50,000 unregistered pharmaceutical stores as against the 2,000 registered outfits in Lagos.

"You cannot fight drug counterfeiting and have this number of unregistered and unregulated

outfits everywhere keeping drugs where they should not be kept," he says.

For the President of the Association of Pharmacists in Gabon, Dr. Serge Issembbe, illegal sale of drugs is the major challenge in his country.

Issembbe said that the law controlling such sales in open markets and streets should be strengthened in Africa because they encouraged faking.

"Because these people are not authorised, they can fake drugs and sell expired drugs," he said.

Issembbe said that the association had been embarking on sensitisation programmes to discourage people, especially women and children, from buying drugs in the open market.

"With our efforts, the government also embarks on raiding some of the markets to rid them of fake drugs."

"This is a very big problem in Gabon and Africa as a whole," he said.

Analysts note that the recognition accorded NAFDAC by the Francophone pharmaceutical organisation is a sign of more good things to come in the fight to rid the continent of drug counterfeiting.

Mr. Anthony Akhimien, the President, Pharmaceutical Society of Nigeria, said: "This forum enables both the French and English-speaking African countries to exchange ideas and acquire skills on how to fight the scourge."

"The forum has also made us to examine new products and fashion out ways to promote best practices in the pharmaceutical industry on the continent," he added.

For Nigeria, the fight against fake and adulterated drugs is ongoing although NAFDAC says that it has reduced its incidence from more than 41 per cent in 2001 to 16.7 per cent in 2006.

Unregistered drugs which stood at 68 per cent in 2001 were reduced to 19 per cent five years later. The result of this milestone achievement by NAFDAC under the leadership of Akunyili is the increase in the production capacity of local pharmaceutical industries to more than 70 per cent in the last seven years.

By 2001, local pharmaceutical industries were producing less than 25 per cent of the country's drug needs, but are currently producing more than 40 per cent. But more heart-warming is the news that the ban on made-in-Nigeria drugs has also been lifted by other West African countries. The benefit is that many drugs produced in Nigeria, including paracetamol brands, multivitamins and antibiotics, are now being marketed in many African countries.

Expectedly, the gains recorded in the war against drug counterfeiters have inflicted pain on the perpetrators NAFDAC has so far secured 45 convictions, while 60 cases are pending in court.

For Akunyili, "these short-term wins have earned us the respect of consumers and the support and goodwill of the government." Mr. Elvis Emeceta, the President of the Nigerian-Chinese Chamber of Commerce, sums it up by saying that "Africa will remain eternally grateful for Akunyili for challenging the status quo and fighting the drug lords to almost a standstill."

"This is because global drug marketing and distribution is a cartel; but she has challenged it and broken it down," Emeceta says that a critical assessment of Akunyili's job shows that many pharmaceutical companies have been revived and are back to business.

"Even her very life was at stake as she was almost killed, while the lives of the staff were threatened and NAFDAC properties across the country were destroyed because of the battle against fake and counterfeit drugs," Emeceta notes.

As the Federal Government strives to reverse the negative image of the country abroad, it is the responsibility of all corporate organisations and individuals to assist in this direction.

The NAFDAC effort is one of such steps, and it is in the right direction.

(NAN Features)

Between Fashola and Akunyili

By Ozo Sim Okeke

Of all heads of federal agencies appointed since the restoration of democracy in Nigeria on May 29, 1999, the Director General of the National Agency for Food and Drug Administration and Control (NAFDAC), Prof. Dora Akunyili, stands out. And of all the state governors who assumed office on May 29, 2007, Babatunde Fashola of Lagos State is ahead. They both should be of interest to students of leadership and societal mobilisation. In a very complex and diverse society like ours where many people are understandably cynical about their leaders, how have Gov Fashola and Mrs Akunyili charmed the popular imagination? What lessons could be learned from these public officers?

Most Nigerians are under the impression that a number of laws have been made in the last decade or so which have collectively strengthened NAFDAC's operations. But this is not correct. No such laws have been enacted, not even one. Akunyili has relied solely on the act establishing NAFDAC which came into being during the military regime in the 1990s. What accounts for the brand new NAFDAC under Prof Akunyili's leadership is a typical example of the fundamental difference an individual can make in an organisation or the larger society. In the same manner, the phenomenal success which the Lagos State Government has recorded in the last one year does not derive from the new laws which the government has enacted but from those inherited from the preceding administration. Lagosians were startled recently when the Governor explained that he did not create any new law which could be said to be responsible for the dramatic improvement in revenues from land and property registration. Indeed, new laws are not responsible for the astronomical increase in internally generated revenue from N6 billion to N10 billion a month. All he has done thus far is merely to enforce existing laws.

This is an extremely important

Fashola and Akunyili are the face of a new generation of Nigerian leaders, successful, committed, far-sighted and with an acute sense of self worth

point. Nigeria is not short of laws to make for good governance and cause the country to develop. If anything, we have a plethora of laws, rules and regulations. But they are anything but operational. If the appropriate authorities had got the will to apply a substantial bit of the laws, bribery and corruption, for instance, would not have been the monster it is. Perhaps, there would not have been any need for anti-corruption bodies like the Economic and Financial Crimes Commission (EFCC). The Police alone would have been enough to tackle this problem, thus preventing it from escalating into a hydra-headed social monster. There is unfortunately in contemporary Nigeria very little will to allow the law to take its course. Though election rigging is a criminal offence, not one person has ever been prosecuted for it. The result is that thousands of people are emboldened and encouraged to engage in more brazen electoral crimes. Crime pays.

There are scarcely things which can destroy a nation as much as the failure or refusal to be law abiding. Insecurity is the first natural consequence of lawlessness. Somalia is a perfect example of what students of international politics now call failed states. Other examples in Africa are Sierra Leone and Liberia during their catastrophic civil wars. Nigeria is no failed state, but critics regard it as a weak state or a failing one because of the weakness of the state institutions, especially the security apparatus and the regulatory agencies. It is, therefore, heart-warming to find public officers like Fashola and Akunyili who insist we all play by the rules.

These two individuals have

elegantly demonstrated that Nigeria is not as deeply divided along the primordial lines of ethnicity, regionalism, gender and religion as is often portrayed. Support for them has come from all and sundry. Akunyili is a dedicated Christian from Anambra State, but just before the 2007 general election there was a frenetic campaign for her to run for the presidency; and the campaign was led mostly by Northern Muslim women who financed it with their own personal resources. In Lagos State, solidarity with Fashola in the determination to implement the grand vision of transforming the state to an authentic 21st century mega-city has broken all barriers, including political party lines. The other day Governor Peter Obi of Anambra State granted a major interview in which he singled out Fashola for commendation. Does anyone care about Fashola's religion or ethnic group?

Nigerian rulers often resort to divisive politics and manipulation of primordial differences because they have nothing to offer. Public officers like Fashola and Akunyili who are out to work for the common good have no need for such unconscionable and obfuscating tricks. The public recognises this fact and supports these officers. And this goes to prove that the notion that Nigerians are difficult to lead is utterly wrong-headed. Despite the heterogeneous composition of our country, it may well be one of the easiest countries to govern. The problem has been the quality of people inflicted on us as leaders. Brigadier General Mohammed Marwa, for instance, became most admired across the country as a public officer not when

he was the military governor of Borno State—which belongs to his own North East geopolitical zone—but when he served as the Lagos State governor because he proved his mettle here. In the words of the venerable erstwhile country's vice president, Dr Alex Ekwueme, Nigeria is a miracle waiting to happen.

Nigeria will become an admired nation when our political leaders and public officers begin to set their sights on global standards, as Fashola and Akunyili do. Though NAFDAC operates in a corruption-ridden Third World country, Akunyili has been working towards making it one of the most internationally respected regulatory agencies. She wants NAFDAC to be respected everywhere like the Food and Drug Administration of the United States. She may not have succeeded, but she is certainly on the way. Gov Fashola has a similar outlook. Unlike most Nigerian governors who make a show of providing the most rudimentary of basic infrastructure in their states, Fashola is inspired by the powerful example of Lee Kuan Yew of Singapore who, within a generation, turned the near infinitesimal backwaters of a nation with no natural resources into one massive economy and a most orderly and beautiful society. Fashola feels challenged by Singapore's fascinating feat. He is obsessed with modernisation.

Fashola and Akunyili are the face of a new generation of Nigerian leaders, successful, committed, far-sighted and with an acute sense of self worth. They work with an infectious sense of urgency because the Nigerian condition is desperate. To borrow the biblical language, they have come to serve, and not to be served. May their tribe of authentic servant leaders grow from strength to strength. May their tribe form enough critical mass sooner than later. Things just have to change.

Mr. Okeke, an insurance expert, writes from Lagos.

Dora Akunyili: The Amazon chases history

Nnamdi Okosieme
Lagos

I can hardly be open to doubt that Nigeria is lagging behind like a huge timber, a debilitating image problem. Despite having cast of the enslaving yoke of military rule since 1999 the country has remained at a crossroads as corruption, human rights abuses and sundry anti-social behaviours continue to create problems for the country on the international scene.

In the first leg of the Obasanjo administration, which ended in 2003, the politicians who took over from the military against the expectation of the Nigerian and international public appeared to have learnt nothing from the past as they freshly engaged in looting of public funds, assassination of political opponents and rigging of elections. The same scenario continues today. It was thus no surprise that the Olusegun Obasanjo administration worried about the rather unpleasant situation it was committing over a N100 million to an image laundry project many Nigerians believe would not achieve results.

Yet despite the
p o o r

international image, Nigeria does boast people in government who have proved that it is possible even in the face of an avalanche of temptation and a deluge of threats to their lives, serve the public untainted. Dora Nkeim Akunyili, Director-General of the National Agency for Food, Drugs Administration and Control (NAFDAC) clearly belongs in this category.

Last week news broke that Akunyili may have been nominated for this year's Nobel Peace prize. It was heart-warming news for many who have monitored her performance since 2001 when she was appointed boss of NAFDAC. According to the report Akunyili was nominated for her determination to rid Nigeria of the menace of fake and adulterated drugs. Although Geir

Lundestad, the non-voting secretary of the Nobel Peace prize committee failed to conform whether Akunyili was indeed on the list, which includes high profile figures as United States (US) president, George Bush, former US Secretary of State, Colin Powell and Ukrainian president, Viktor Yushchenko, the report said the possibility was indeed high.

The prospect of Akunyili going down in history, as the first Nigerian to win the Nobel Peace prize and the second to win a Nobel prize is indeed appealing. Should it come to pass it would be an honour richly deserved for Akunyili represents a beacon of hope for Nigerians. Hope that despite the crushing corruption, the mindless pillaging of national resources and the neglect of the welfare of the masses of the people, there may still be a new Nigeria.

Before she took over the administration of NAFDAC in 2001 the body was just one of those bodies that drained the resources of government activities and did not in any way impact on

the lives of the people for whom they were set up. Akunyili's coming changed all that. With her in charge NAFDAC has become very much part of the lives of the people to the extent of its warfare on the vendors of death-importers, manufacturers and distributors of fake and adulterated drugs. For these people Akunyili has become a veritable nemesis. Since 2001 she has taken the battle to their doorsteps destroying billions of naira worth of drugs, which would have sent millions of her countrymen to their early graves. And it has not been without some risks. In December 2003 an attempt was made on the life of Akunyili while she was on her way to her hometown to spend the Christmas holidays. The assassination attempt met with national and international outcry. Transparency International (TI), the anti-corruption watchdog reacted angrily. In a statement released in January 2004 TI said:

"The attack on Dr Dora Akunyili highlights the perils faced by those determined to root out corruption. The assassination attempt on Dr Akunyili illustrates the threats faced by corruption fighters worldwide, whose acts of bravery challenge those bent on disrupting law and order and undermining democracy. We call on the Nigerian authorities to investigate this assassination attempt and prosecute those

responsible for this heinous act."

The reaction from TI was not unexpected. The body had since she assumed office followed closely her "courage and incorruptible stance. Their satisfaction and pleasure at her performance had induced TI in May 2003 to award her the TI Integrity Award.

The award was one of many she had been bestowed with since 2001, the latest coming in April this year from the Pan Ndi-Igbo Foundation in the United States of America. She was one of three Nigerians who were honoured by the foundation. She was bestowed with a Diamond Leadership Award. Others who received awards were the celebrated writer Chinua Achebe who was given a Lifetime Achievement Award and Chief Simon Okeke, the chairman of the Police Service Commission. In announcing the award to Akunyili the foundation said:

"Director General of the National Agency for Food, Drug Administration and Control (NAFDAC), Dr. (Mrs.) Dora Akunyili, on behalf of Ndi-Igbo in the Diaspora under the auspices of the Pan Ndi-Igbo Foundation (PNF USA), we congratulate you on and support you for your assiduous task to curb corruption by ensuring that legitimate drugs are administered to the citizens of Nigeria. We applaud and commend you for your personal sacrifice to improve the health of Nigerians by working hard to eliminate fake drugs from the market. In view of this fact, we want to honour you and say thank you. We, hereby, declare that you are the most deserving of the 2005 PNF USA Diamond Leadership Award."

Such is her relevance in Nigeria today that though she has signalled her intention to quit when her tenure expires next year, Nigerians have been calling on her to rescind that decision. For the average Nigerian and even those in power, the thought of a resignation to the vendors of death, which they fear would be the reality upon Akunyili's exit, is unthinkable. Recently when Akunyili paid a visit to Donald Duke, the governor of Cross River State, duke described her decision not to seek a return to office as "painful to most Nigerians", and called on her to have a rethink.

Even beyond calls for her to remain as NAFDAC boss after 2005 there are those who are already thinking of an Akunyili 2007 Presidency Project. Those behind this idea think that Nigeria could do with a transparent and dedicated leadership that an Akunyili presidency would be sure to provide. Recently, Kola Johnson, one of those disposed to the idea wrote that Akunyili:

"Has been in the system and already acclimatized to it. For her, it is no novel habitat. So it could rightly be averred that her shadows would not loom so menacingly as to send the power oligarchs to the disconcerting stupor of fear. This it could rightly be assumed is because being in the system would have put her in a vantage place to forge a pragmatic new balance between the divergent world of abstract idealism on one hand, and practical realism on the other hand, without sacrificing the value of excellence which has been her hallmark."

The goodwill she enjoys cuts across tribal barriers and equally as important is the fact gathered on reliable authority, that she has the favour of the president. Now, therefore the time to forge a formidable front by exploiting the potent force inherent in the concerted populist will - towards the liberation struggle of freedom from the yoke of fellow native oppressors."

A Nobel Peace prize would indeed be fitting for an indefatigable fighter for transparency, someone who all through her life has been spurred by the will to excel and to serve.



Akunyili's love for war veterans

Grandstand

by

Ken Ugbechie 0803-436-4524

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EACH time you meet her, you would not miss the glint of brilliance in her eyes. But that is not all there is to this amazing amazon of uncommon intelligence. She easily overawes you with her passion for her job and patriotism to her fatherland.

She is not the type that hypes her commitment to Project Nigeria. But it is all over her that she is much more committed than the rest of us. And not for lucre's sake. Never! She has proved by her deeds and words that she's too expensive, in fact too decent, to be bought over with the narcotics baron's money.

Talk about proper breeding. Professor Dora Akunyili, pharmacist, pharmacologist, scholar, administrator, leader and daughter of Chief Paul Young Edemobi has it. What about family value? Oh, the grandmother and mother of six has proved that it is possible to have a successful career and still keep the home front healthy and intact.

In service and leadership, she has practically raised the stakes for the public servant. In her and through her, we see a new culture of service in public office, a culture that puts the nation above self, a culture that promotes dignity in labour over and above perfunctory gratification, indeed a culture of selflessness in service.

Again, this is not all there is to this woman who was always first in her class throughout her high school career. There is yet another virtue that issues forth from the bosom of her heart. It is her humaneness, her undying love for humanity, for the hopeless, for the downtrodden. There are yet other virtues that spew forth from Nigeria's Madam NAFDAC. And each time she flaunts them, she convicts the rest of us. She reminds us of our inherent wickedness, insensitivity and brutal tendency to kill in order for us to live. We even tried to kill her on that fateful December 26, 2003. You see what I mean? We are always killing our best. The same way we killed Dele Giwa, A.K. Dikibo, Bola Ige and Murtala Muhammed. But our Dora is fated to live and not die. And she lives, not for herself alone but she lives for all of us.

Now, she has done it again. She has taken her selfless service and overflowing milk of human kindness to the inmates of

the Oji River rehabilitation camp in Enugu. I bet you don't know these people. You may only have heard of them. But I know them. I have been with them. I was their guest about two years back. They are war veterans—battered and broken by the 30-month civil war that shook this nation from 1967-1970. These were once mighty men of valour, valiant and full of verve. They were once able-bodied men, fit enough to pull the trigger, fire a rocket, detonate a bomb and intercept the enemies' bullets. Yes, they did intercept bullets and for that their lives were interjected, brutally dismembered. Some lost their hands, some their legs.

And at the end of the war, the most the federal government could do for them in the spirit of reconstruction, reconciliation and rehabilitation was to shoo them into a cluster of make-

is Oji River rehab camp. And to rub in the pain, some of the inmates had been abandoned by their families. Yet, they are citizens of a country that is so rich in petro-dollar, so rich that she doesn't know what to do with such huge money hence she now builds bridges over dry land in Abuja and plays host to other nations of the world in the name of sports, tourism and culture.

Now, it has taken Akunyili to remind us that the war is still on in the hearts of the inmates of the camp. Our Dora of Integrity recently challenged all of us, particularly the federal government and the governments of the South East states, when she extended her love for humanity to the war veterans. Early this year, she was honoured as Man of the Year by Silverbird Television. The award came

and the hopeless.

But we forget that a war is not over if the bruises and scars are not healed. The inmates of Oji River camp represent the marks and scars of the war. And with their pains and trauma, they assail us everyday with a conviction—we are still at war even in our hearts. And this hurts more than the actual war itself.

Let's not pretend. We are still at war. Anybody who has seen the war veterans at Oji River camp would both cringe and wince. What with their bleary, blood shot eyes, their hurting backsides, overgrown beards and shaggy hairs interspersed with shafts of grey, or their weak and bent knees and scrawny fingers for those who still have theirs intact. The picture of the war veterans is a picture of pain, a story fit only for fables, in fact, an unbelievable story of neglect and insensitive aloofness on the part of government.

That is why I hail the spirit of Akunyili, a woman who has garnered over 300 local and international awards, since April 2001 when she assumed office as NAFDAC boss, far more than any Nigerian in contemporary history.

I am ever enchanted by the Akunyili fragrance. It is a fragrance that has added taste to the Obasanjo government. But wait a minute. Don't you think we need this fragrance to spice up other agencies that have practically gone putrid? We've just made a mess of a census, the same way we bungled elections in 2003 and are working even harder to do same in 2007(?), the same way we have refused to apply probity in computing our accruals from crude oil sales. No doubt, this country would get better if we can clone other Akunyilis to preside over the National Population Commission (NPC), NNPC, NDDC, INEC or even the nation.

This woman has done us proud. She has brought glory to Nigeria, a country long starved of garlands. My prayer is that not only God would remember your labour of love, mankind also will find a befitting space for you in its hall of fame.

The essence of giving is not in the size of the gift but in the spirit of the gesture. The Akunyili exemplar has added a rich fragrance to our savage culture of abandoning our old, the invalid, the unemployed and unemployable, the poor and the hopeless.

shift shanties in Oji River area and turn its back at them. That's rehabilitation, my dear.

As I write this, it is about 36 years since the war ended but it is still being fought in the hearts of the Oji River inmates. The war rages in their bruised hearts, scared by government neglect and encumbered by the burden of ageing. Ageing in poverty in itself is a burdensome cross. It is worse when in addition, you are isolated like the war veterans. It assumes a horrendously worrisome tenor when the person is limbless without hand or without leg, sometimes both.

That is the pathetic sight that confronts you as you step into the rustic commune that

with a prize of N1 million. But Madam NAFDAC is not known for eating alone. Her passion, indeed, obsession to be her brothers' keeper took the better part of her. Pronto, she sourced more cash from the corporate world. De-United Food Industry Limited and Fildson Healthcare etc, were on hand to pump up the cash volume to N3 million which she took to the war veterans. Somebody would yell, what a pitance! Come off it. The essence of giving is not in the size of the gift but in the spirit of the gesture. The Akunyili exemplar has added a rich fragrance to our savage culture of abandoning our old, the invalid, the unemployed and unemployable, the poor

Imoke Commends NAFDAC DG

After receiving the coveted highest award from Gabonese Pharmaceutical Federation, Director-General of National Agency for Food and Drug Administration and Control (NAFDAC), Prof. Dora Akunyili has been praised by the Cross River State Government for her selfless and relentless service to the nation.

Governor Liyel Imoke of Cross River State's commendation of Professor Akunyili's dogged fight against fake drugs came on the heels of special recognition and tribute paid to her by President of Gabon, El-Aadj Omar Bongo during a cour-

tesy visit to the oil rich French-speaking Africa country recently.

Imoke said millions of Nigerians are watching closely the good works of the NAFDAC Director-General and her passion for safeguarding lives through promotion of quality drugs and wholesome foods.

The Governor further commended NAFDAC's prompt intervention on the food poison saga which reportedly killed some people and left several others hospitalized in the state recently while assuring the Agency of his government's co-operation and support in forestalling future occurrence through sustained public enlightenment campaign and

workshops.

His words "I want to place on record and also commend you for the excellent and selfless services, you are a role model to many people and the nation is appreciative of your tireless efforts to save lives. I wish you long stay in service".

Responding, Director-General of NAFDAC, Prof. Dora Akunyili thanked the Governor for his kind words and eagerness to partner with the Agency in educating the citizenry about the dangers involved in use of banned hazardous agrochemicals and wrong use of pesticides by farmers and grain merchants in preserving beans, maize and other grains.

The Fact Finder, June 2008, p. 8

Akunyili is God-sent, says EFCC boss

THE chairman of the Economic and Financial Crimes Commission (EFCC), Mrs. Farida Waziri has lauded the Director-General of the National Agency for Food, Drugs Administration and Control (NAFDAC), Prof. Dora Akunyili.

The EFCC boss, who paid a courtesy visit to Akunyili, recently was visibly impressed with the galaxy of over 350 national and international awards and plaques on display in her office in Abuja.

Mrs. Waziri described the NAFDAC boss as "God-sent and a shining role model that the country is proud to have."

She observed that the advent of Prof. Akunyili at the helms of NAFDAC regulatory activities has redefined and raised public consciousness and reawakened the battle against fake drugs and substandard products in the country.

Her words: "I came to congratulate her on the

Abuja

job she is doing for this great country. Before she came on board, I knew there was rot in the country but never dreamt that a fellow human being could get to the level of selling poison that is damaging to health, all in the name of making money."

The EFCC chairman solicited the support and co-operation of NAFDAC in the ongoing fight against corruption and economic crimes, especially in terms of information sharing, intelligence networking and collaboration in public enlightenment campaign.

In her reaction, Prof. Akunyili said women in public offices and positions of trust must be result-oriented and exhibit a high sense of integrity, probity and dedication to duty in order to encourage government to invite more women to serve the country.

The Nation, September 1, 2008, p. A6

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Dora Nkem Akunyili

"The War Against Counterfeit Medicine: My Story", chronicles the ills of fake / counterfeit medicines, substandard food, cosmetics and related products. The author, Dora Nkem Akunyili, highlights her experience as Director General of Nigeria's National Agency for Food and Drugs Administration and Control (NAFDAC). She waged an all out war against the hydra-headed monster, with the aim of safeguarding the lives of Nigerians. The author takes us through the harrowing fright of sustained intimidations and threats which culminated in a failed assassination attempt on her life. Not deterred, she relentlessly continued the war against counterfeit medicine, employing ingenious and novel strategies to outwit the counterfeiters. The result was a tremendous drop in the level of fake / counterfeit drugs, substandard food, cosmetics and related products in Nigeria, and indeed the West African sub-region.

"The War Against Counterfeit Medicine: My Story" is a must read, not only for food and drug regulators, but also for members of the general public and the world at large. As a tool for public awareness, it will sensitise individuals, organisations and governments around the world to recognise the dangers posed by counterfeit medicine and thus encourage the establishment of an international coalition in the war against counterfeit medicine.

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